Central Administration of Pharmaceutical Care
General Administration for Drug Utilization and Pharmacy Practice

Egyptian National Drug Formulary

Respiratory System Medications

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Contents

Preface

The *Egyptian National Drug Formulary* is published by the **Egyptian Drug Authority (EDA)**. It has been developed by the **General Administration of Drug Utilization and Pharmacy Practice**, under the supervision of the **Central Administration of Pharmaceutical Care**, and reviewed by the **Committee of Pharmacy Practice Guides and National Drug Lists** at the EDA.

The *Egyptian National Drug Formulary* aims to provide pharmacists and other healthcare professionals with accessible, evidence-based, and reliable information on medications available in the Egyptian drug database, supporting sound clinical decision-making and promoting the rational use of medicines across healthcare settings.

This formulary serves as a reference guide that should be applied in conjunction with professional clinical judgment. Every effort has been made to ensure the accuracy and completeness of the information at the time of publication. However, as medical knowledge and best practices continue to evolve, users are encouraged to apply their professional judgment when using this formulary.

Egyptian National Drug Formulary Manual Respiratory Drugs

The Egyptian Drug Formulary (respiratory medications) contains a list of medicines registered in the Egyptian drug database, included in the essential medicines list, or widely used in the Egyptian pharmaceutical market. It is designed as drug monographs classified pharmacologically and arranged alphabetically. There is a pharmacologically classified drug index at the beginning of the document and another alphabetically classified index at the end.

The Egyptian National Drug Formulary (respiratory medications) presents detailed practical information for healthcare providers about each medicine. Each monograph includes:

1. Generic name.
2. Dosage forms/strengths available in Egypt from the EDA database.
3. Route of administration.
4. Pharmacological category and ATC code.
5. Indications: Labeled indications.
6. Dosage regimens for adults and pediatrics.
7. Dosage adjustments if needed.
8. Contraindications.
9. Adverse drug reaction.
10. Monitoring parameters.
11. Drug interactions: That imply avoidance or considering modifications.
12. Pregnancy and lactation.
13. Administration: Detailed administration information for all routes [parenteral (preparation concentrations, compatibility with diluents, infusion rate, precautions during administration), oral (food correlation)].
14. Warnings/precautions.
15. Storage conditions:
    - For reconstituted vials, apply the mentioned storage conditions only if prepared in aseptic techniques and ISO-controlled conditions according to USP 797 standards; otherwise, discard immediately if not used.
    - USP develops standards for compounding medications to help ensure patient benefit and reduce risks such as contamination, infection, or incorrect dosing.

N.B. Referral to the product leaflet is needed for other specific formulation considerations.

Respiratory Disorders Formulary

This document includes medications that contribute to the management of respiratory disorders. Therapeutic classes include: anti-histaminic agents, anti-muscarinic agents, anti-tussive (cough suppressant) agents, beta2-adrenoceptor agonists, decongestants, human alpha 1-proteinase inhibitors, inhaled corticosteroids, leukotriene receptor antagonists, mucolytics and expectorants, xanthines, respiratory stimulants, lung surfactants, and antifibrotics.

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We sincerely acknowledge and appreciate their exceptional efforts and meaningful contributions to this significant national endeavor.

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Abbreviations

% w/v	Weight/Volume Percentage
°C	Degree Celsius
5-ASA	5-Aminosalicylic Acid
ACTH	Adrenocorticotropic Hormone
AGEP	Acute Generalized Exanthematous Pustulosis
ALT	Alanine Aminotransferase
AM	Ante Meridiem "Before Midday."
AST	Aspartate Aminotransferase
ATC	Anatomical Therapeutic Chemical
BMD	Bone Mineral Density
BUN	Blood Urea Nitrogen
Cm	Centimeter
CNS	Central Nervous System
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous Positive Airway Pressure
CrCl	Creatinine Clearance
CYP450	Cytochrome P450
DRESS	Drug Reaction With Eosinophilia And Systemic Symptoms
D5NS	5% Dextrose in Normal Saline
D5W	Dextrose 5% in Water
DIP	Dry Powder Inhalers
ECG	Electrocardiogram
eGFR	Estimated Glomerular Filtration Rate
EIB	Exercise-Induced Bronchoconstriction
ER	Extended Release
FEV1	Forced Expiratory Volume 1
FiO2	Fraction of Inspired Oxygen
g	Gram
h	Hour
HCL	Hydrochloride
HDL	High-Density Lipoprotein
HIV	Human Immunodeficiency Virus
HPA	Hypothalamic-Pituitary-Adrenal Axis
ICS	Inhaled Corticosteroids
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IM	Intramuscular
INR	International Normalized Ratio

INSURE	Intubation Surfactant Extubation
IOP	Intraocular Pressure
IPF	Idiopathic Pulmonary Fibrosis
IU	International Units
IV	Intravenous
kg	Kilogram
L	Liter
LABA	Long-Acting Beta-Agonist
LD	Loading Dose
LDL	Low-Density Lipoprotein
LISA	Less Invasive Surfactant Administration
MAOIs	Monoamine Oxidase Inhibitors
mcg	Microgram
mcg/kg	Microgram Per Kilogram
mg/kg	Milligram Per Kilogram
mg/mL	Milligram Per Millilitre
MD	Maintenance Dose
MDI	Metered-Dose Inhalers
mg	Milligram
min	Minute
mL	Milliliter
NaCl	Sodium Chloride
NMDA	N-Methyl-D-Aspartate
NP	Neuropsychiatric
NS	Normal Saline
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
PEF	Peak Expiratory Flow
pH	Potential Hydrogen
PIL	Patient Information Leaflet
PM	Post Meridiem "After Midday."
PT	Prothrombin Time
QTc	Corrected Qt Interval
RDS	Respiratory Distress Syndrome
SC	Subcutanous
SCr	Serum Creatinine
SR	Sustained Release
SJS	Stevens-Johnson Syndrome
SSRI	Selective Serotonin Reuptake Inhibitors
TB	Tuberculosis
TEN	Toxic Epidermal Necrolysis

ULN	Upper Limit Of Normal
UPCR	Urine Protein-Creatinine Ratio
Vd	Volume Of Distribution
µg	Microgram

Anti-Histaminic Agents

Cetirizine

Generic Name	Cetirizine
Dosage Form/Strengths	**Oral drops:** 10 mg/1 ml **Oral syrup or solution:** 1 mg/ ml **Film-coated tablets:** 10 mg **Chewable tablets:** 10 mg **Solution for IV injection:** 10 mg **Ophthalmic solution:** 2.4 mg/ 1 ml And combinations
Route of Administration	Oral, IV, Ophthalmic
Pharmacologic Category	Histamine H_1 antagonist, second generation: piperazine derivative. **ATC: Oral:** R06AE07, **Ophthalmic**: S01GX12
Indications	**Oral** (in adults and children 2 years and above) • Relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis. • Relief of symptoms of chronic idiopathic urticaria. **Intravenous** Treatment of acute urticaria in adults and children 6 months of age and older. **Ophthalmic** Treatment of ocular itching associated with allergic conjunctivitis. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Dosage Regimen	**Adult dosing** **Oral:** 10 mg once daily. **Ophthalmic:** One drop in each affected eye twice daily. **IV**: Adults and adolescents ≥ 12 years of age: 10 mg once every 24 hours as needed for acute urticaria. **Pediatric dosing** **Oral** • **Children aged from 2 to 6 years:** Oral: 2.5 mg once to twice daily. • **Children aged from 6 to 12 years:** Oral: 5 mg twice daily (or 10 mg once based on severity). • **Adolescents over 12 years of age:** Oral: 10 mg once daily. **Ophthalmic** **Children aged 2 years and older**: one drop in each affected eye twice daily. **Intravenous** • **Children 6 months to 5 years**: IV: 2.5 mg once a day as needed for acute urticaria. • **Children 6 to 11 years**: IV: 5 mg or 10 mg once a day as needed for acute urticaria, depending on the severity of symptoms. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for

Cetirizine

<table>
<tr><td></td><td>combinations.</td></tr>
<tr><td>Dosage Adjustment</td><td>
<u>Renal Impairment</u>
<u>Oral</u>
<table>
<tr><th>Group</th><th>Estimated Glomerular Filtration Rate (eGFR) (ml/min)</th><th>Dosage and frequency</th></tr>
<tr><td>Normal renal function</td><td>≥ 80</td><td>10 mg once daily</td></tr>
<tr><td>Mildly decreased renal function</td><td>50 < 79</td><td>10 mg once daily</td></tr>
<tr><td>Moderately decreased renal function</td><td>30 < 49</td><td>5 mg once daily</td></tr>
<tr><td>Severely decreased renal function</td><td><30 not requiring dialysis treatment</td><td>5 mg once every 2 days</td></tr>
<tr><td>End-stage renal disease</td><td>< 10 requiring dialysis treatment</td><td>Contraindicated</td></tr>
</table>
<u>Intravenous</u>

Moderate and severe renal impairment and in patients on dialysis: No dose adjustment is required. Monitor for antihistaminic side effects.
In pediatric patients less than 6 years with severe renal impairment, avoid use.

<u>Hepatic Impairment</u>

Oral: No dose adjustment is needed. Monitor for antihistaminic side effects.
IV: In pediatric patients less than 6 years with severe hepatic impairment, avoid use.

N.B. Refer to the manufacturer’s PIL if there are specific considerations for combinations.
</td></tr>
<tr><td>Contra-indications</td><td>
<u>Systemic</u>

Known hypersensitivity to cetirizine, levocetirizine, hydroxyzine, or any component of the formulation.
End-stage renal disease (eGFR below 15 ml/min) and patients undergoing hemodialysis.
IV: Pediatric patients less than 6 years with impaired renal or hepatic function.

<u>Ophthalmic</u>
None.
N.B. Refer to the manufacturer’s PIL if there are specific considerations for combinations.
</td></tr>
<tr><td>Adverse Drug Reactions</td><td>
<u>>10%</u>
Nervous system: Drowsiness, headache.
<u><2%</u>
</td></tr>
</table>

Cetirizine

	Cardiovascular: Cardiac failure, chest pain, edema, facial edema, flushing, hypertension, lower extremity edema, palpitations, peripheral edema, syncope, tachycardia. **Dermatologic**: Acne vulgaris, alopecia, bullous rash, cutaneous nodule, dermatitis, diaphoresis, eczema, erythematous rash, furunculosis, hyperkeratosis, hypertrichosis, maculopapular rash, pallor, pruritus, seborrhea, skin photosensitivity, skin rash, urticaria, xeroderma. **Endocrine and metabolic**: Decreased libido, dehydration, diabetes mellitus, heavy menstrual bleeding, hot flash, increased thirst, intermenstrual bleeding, and weight gain. **Gastrointestinal**: Abdominal pain (children: 4% to 6%), ageusia, anorexia, aphthous stomatitis, constipation, dental caries, diarrhea (children: 2% to 3%), dysgeusia, dyspepsia, enlargement of abdomen, eructation, flatulence, gastritis, hemorrhoids, increased appetite, melena, nausea, sialorrhea, stomatitis, tongue discoloration, vomiting, xerostomia (adolescents and adults: 5%). **Genitourinary**: Cystitis, dysmenorrhea, dysuria, hematuria, leukorrhea, mastalgia, urinary frequency, urinary incontinence, urinary retention, urinary tract infection, vaginitis. **Hematologic and oncologic**: Hemophthalmos, lymphadenopathy, purpuric disease, rectal hemorrhage. **Hepatic**: Hepatic insufficiency. **Hypersensitivity**: Angioedema, tongue edema. **Nervous system**: Abnormality in thinking, agitation, altered sense of smell, amnesia, anxiety, ataxia, confusion, depersonalization, depression, dizziness, emotional lability, euphoria, fatigue (4% to 6%), hyperesthesia, hypertonia, hypoesthesia, impaired concentration, insomnia (≤9%), malaise (≤4%), migraine, myasthenia, nervousness, nightmares, pain, paralysis, paresthesia, rigors, sleep disorder, twitching, vertigo, voice disorder. **Neuromuscular and skeletal**: Arthralgia, arthritis, asthenia, back pain, hyperkinetic muscle activity, lower limb cramp, myalgia, myelitis, osteoarthrosis, tremor. **Ophthalmic**: Accommodation disturbance, blepharoptosis, blindness, conjunctivitis, eye pain, glaucoma, periorbital edema, visual field defect, xerophthalmia, ocular hyperemia. **Otic**: Deafness, otalgia, ototoxicity, tinnitus. **Renal**: Polyuria. **Respiratory**: Bronchitis, bronchospasm (children: 3%), dyspnea, epistaxis (children: 4%), hyperventilation, increased bronchial secretions, nasal polyposis, pharyngitis (2% to 6%), pneumonia, respiratory system disorder, rhinitis, sinusitis, upper respiratory tract infection. **Miscellaneous**: Fever. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Monitoring Parameters	Monitor for relief of symptoms, sedation, mental alertness, and anticholinergic effects.

Cetirizine

	N.B. Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Drug Interactions	***Risk X: Avoid combination*** Alcohol (Ethyl), Pitolisant. ***Risk D: Consider Therapy Modification*** Benzylpenicilloyl Polylysine, CNS Depressants. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Pregnancy and Lactation	**Pregnancy** No evidence of fetal harm in human or animal studies. Cetirizine may be used with caution when needed in pregnancy. **Lactation** Use is not recommended. Cetirizine passes into breast milk. A risk of side effects in infants cannot be excluded; it is not known whether the systemic absorption resulting from topical ocular administration could produce detectable quantities in human breast milk. Caution should be taken. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Administration	**Oral** • **Tablets**: Administered with water. May be administered with or without food. • **Chewable tablet:** Tablet to be chewed before swallowing. • **Liquid:** Administered with an accurate measuring device. **Intravenous** Administer as an IV push over 1 to 2 minutes. **Ophthalmic** • Do not touch the dropper tip to eyelids, surrounding areas, or any surface. • Remove contact lenses before administration. • After instilling drops, wait ≥10 minutes before inserting contact lenses. Do not wear contact lenses if your eyes are red. **N.B.** Refer to the manufacturer's PIL if there are specific considerations**.**
Warnings/ Precautions	**Sedation and somnolence** • Caution when driving a car or operating potentially dangerous machinery. • Avoid concurrent use with alcohol or other CNS depressants, as additional impairment in CNS performance may occur. **Urinary retention** Cetirizine may increase the risk of urinary retention. Therefore, caution should be taken in patients with risk factors of urinary retention (e.g., spinal cord lesion, prostatic hyperplasia). **Epileptic patients** Caution in epileptic patients and patients at risk of convulsions. **Allergy skin tests** Antihistamines inhibit the response to allergy skin tests. A wash-out period (of 3 days) is required before performing an allergy skin test. **Pruritus and/or urticaria**

Cetirizine

	Pruritus and/or urticaria may occur when cetirizine is stopped, even if these symptoms were not present before treatment initiation. **Ophthalmic use** Caution should be taken not to touch the eyelids or surrounding areas with the dropper tip of the bottle to avoid injury to the eye and to prevent contamination of the tip and solution. should not be instilled while wearing contact lenses. Keep the multi-dose bottle closed when not in use. Discard the single-use container after using it in each eye. **Pediatric population** The use of the film-coated tablet formulation is not recommended in children under 6 years of age, as this formulation does not allow for appropriate dose adjustment. It is recommended to use a pediatric formulation of cetirizine. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Storage	IV: Store below 25°C. Oral: Store in a temperature not exceeding 30°C in a dry place. Ophthalmic: Store at a temperature not exceeding 30 °C and after opening, to be used within 28 days. **N.B.** Refer to the manufacturer's PIL if there are specific considerations**.**

Chlorpheniramine maleate

Generic Name	Chlorpheniramine maleate
Dosage Form/ Strengths	**Tablets**: 4 mg **Syrup**: 2 mg/5 ml **Solution for IM, SC, or IV injection**: 10 mg /2 ml, 5 mg/ 1ml.
Route of Administration	Oral, IM, IV, SC
Pharmacologic Category	Histamine H_1 antagonist, first generation; alkylamine derivative. **ATC:** Chlorphenamine: R06AB04
Indications	**Oral (Not recommended for children < 2 years)** • The symptomatic control of acute allergic conditions which respond to antihistamines, including hay fever, urticaria, angioneurotic oedema, allergic/vasomotor rhinitis, food allergy, drug and serum reactions, and insect bites. • Also indicated for the symptomatic relief of itch associated with chickenpox. **Injection (In adults and children aged 2 – 18 years)** Acute urticaria, control of allergic reactions to insect bites and stings, angioneurotic edema, drug and serum reactions, desensitization reactions, hay fever, vasomotor rhinitis, and severe pruritus of non-specific origin.
Dosage Regimen	**Adult dosing** • **Oral:** 4 mg every 4 to 6 hours; maximum daily dose: 24 mg. • **Injection** (IM, IV, or SC): 10 to 20 mg as a single dose; may administer additional doses as needed (maximum daily dose: 40 mg). **Elderly** • **Oral:** The elderly are more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily dose (e.g., a maximum of 12 mg in any 24 hours). **Pediatric dosing** • **Oral** - ***Children 2 to 6 years:*** 1 mg (2.5 ml) every 4 to 6 hours. Maximum daily dose: 6 mg. - ***Children 6 to < 12 years:*** 2 mg (5 ml) or (0.5 tablet) every 4 to 6 hours. Maximum daily dose: 12 mg. - ***Children ≥12 years and adolescents:*** 4 mg (10 ml) or 1 tablet every 4 to 6 hours. Maximum daily dose: 24 mg. • **Injection (**IM, IV, or SC): Should not be used for children < 2 years old and should be used for children < 6 years old under medical supervision.

Chlorpheniramine maleate

	Age / **Dose** (Fixed dosing / Weight-based dosing) **2 to 5 years**: 2.5 mg to 5 mg / 0.20 mg/kg **6 to 12 years**: 5 mg to 10 mg / 0.20 mg/kg **12 to 18 years**: 10 mg to 20 mg / 0.20 mg/kg
Dosage Adjustment	**Renal Impairment** There are no dosage adjustments available. Use with caution in severe renal impairment. **Hepatic Impairment** There are no dosage adjustments available. Use with caution, especially in advanced liver disease
Contra-indications	• Hypersensitivity to chlorpheniramine maleate or any of the excipients. • In patients who have been treated with monoamine oxidase inhibitors (MAOIs) within the last 14 days. • Coma or pre-coma states. • Known brain damage or epilepsy. • Acute asthma. • Premature infants or neonates, because of their increased susceptibility to the antimuscarinic effects.
Adverse Drug Reactions	**Nervous system disorders** **Very common (>10%):** Sedation, somnolence. **Common (1-10%):** Dizziness, headache, impaired concentration ability, abnormal coordination, and psychomotor impairment. **Eye disorders** **Common (1-10%):** Blurred vision. **Gastrointestinal disorders** **Common (1-10%):** Gastrointestinal disturbances such as nausea, vomiting, diarrhea, and dry mouth. **General disorders and administration site conditions** **Common (1-10%)**: Fatigue.
Monitoring Parameters	There are no monitoring parameters needed.
Drug Interactions	***Risk X: Avoid combination*** Aclidinium, Azelastine (Nasal), Carbinoxamine, Cimetropium, Dronabinol, Eluxadoline, Flunarizine, Glycopyrrolate (Oral Inhalation), Glycopyrronium (Topical), Ipratropium (Oral Inhalation), Kratom, Levosulpiride, Mavorixafor, Nabilone, Noscapine, Olopatadine (Nasal), Oxatomide, Oxomemazine, Paraldehyde, Pitolisant, Potassium Chloride, Potassium Citrate, Pramlintide, Revefenacin, Sofpironium, Thalidomide, Tiotropium, Tranylcypromine, Umeclidinium. ***Risk D: Consider therapy modification*** Articaine. Benzylpenicilloyl Polylysine, Blonanserin, Buprenorphine, Cetirizine (Systemic), Chloral Hydrate/Chloral Betaine, Chlormethiazole,

Chlorpheniramine maleate

	ChlorproMAZINE, Clozapine, Daridorexant, Dexmedetomidine, Diphenoxylate, Droperidol, Eszopiclone, Flunitrazepam, Hydroxyzine, Lemborexant, Loxapine, Methotrimeprazine, Opioid Agonists, Oxybate Salt Products, Promethazine, Oxycodone, Rivastigmine, Ropeginterferon Alfa-2b, Scopolamine, Secretin, Trimethobenzamide, Zaleplon, Zolpidem, Zuclopenthixol, Zuranolone.
Pregnancy and Lactation	**Pregnancy** • Inadequate human data is available. • It is preferable to avoid the use of chlorphenamine during pregnancy. • However, it may be considered if potential benefits outweigh potential risks. Use during the third trimester may result in reactions in neonates. **Lactation** • Small amounts of antihistamines are excreted in breast milk. • Chlorpheniramine may inhibit lactation. • Not to be used during lactation unless potential benefits outweigh potential risk.
Administration	**Oral administration** • May be used without regard to food. • **Syrup:** Administer liquid formulations with an accurate measuring device; do not use a household teaspoon (overdosage may occur). **IV, IM, or SC administration**. • When a rapid effect is desired, as in anaphylactic reactions, the intravenous route is recommended. • In the event of a blood transfusion reaction, injection should be given by the subcutaneous route. • **Preparation for IV injection**: may use NaCl 0.9% for dilution to a final concentration of 1mg/ml. The diluted product should be used immediately. • IV injection should be injected slowly over a period of 1 minute. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	***Adverse effects related issues*** • **CNS depression:** Chlorphenamine may cause drowsiness, dizziness, blurred vision, and psychomotor impairment in some patients, which may seriously affect the ability to drive and use machinery. ***Disease-related issues*** • **Epilepsy:** Use with caution due to anticholinergic effects. • **Raised intra-ocular pressure, including glaucoma:** Use with caution due to anticholinergic effects. • **Prostatic hypertrophy and urinary retention:** Use with caution due to anticholinergic effects. • **Cardiovascular disease and severe hypertension:** Use with caution due to anticholinergic effects.

Chlorpheniramine maleate

	• **Bronchitis, bronchiectasis, and asthma:** Use with caution due to anticholinergic effects. • **Hepatic disease:** Use with caution due to anticholinergic effects. It should be avoided in severe liver disease. • **Renal impairment:** Use with caution. • **Thyrotoxicosis:** Use with caution due to anticholinergic effects. • **Pyloroduodenal obstruction:** Use with caution. ***Special populations-related issues*** • **Children and the elderly** are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g., increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion. ***Concurrent medication-related issues*** • **Alcohol:** The effects of alcohol may be increased. So, concurrent use should be avoided. • **Other antihistamine:** Should not be used with other antihistamine-containing products, including antihistamine-containing cough and cold medicines. • **Hypnotics or anxiolytics:** Concurrent use of chlorphenamine with these drugs may potentiate drowsiness. ***Dosage form-related issues*** • **Some dosage forms contain lactose:** Avoid in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption. • **Some dosage forms contain sodium benzoate: So, it should be avoided in neonates.** • **Some dosage forms contain sugar:** So, it should be avoided in patients with rare hereditary problems of fructose intolerance.
Storage	Store below 30°C in a dry place. Protect from light. **N.B.** Refer to the manufacturer's PIL if there are specific considerations**.**

Fexofenadine

Generic Name	Fexofenadine
Dosage Form/Strengths	• **Film-coated tablets:** 60 mg, 120 mg, 180 mg. • **Hard gelatin capsules:** 120 mg, 180 mg. • **Oral suspension:** 30 mg/5ml.
Route of Administration	***Oral***
Pharmacologic Category	Histamine H_1 antagonist, second generation; piperidine derivative **ATC:** R06AX26
Indications	• Relief of symptoms associated with seasonal allergic rhinitis and allergic rhinitis in adults and children from 2 years of age. • Relief of symptoms of urticaria in adults and children from 6 months of age. • Relief of symptoms associated with seasonal allergic rhinitis in adults and children from 12 years of age. • Relief of symptoms associated with chronic idiopathic urticaria.
Dosage Regimen	**Adults and children ≥ 12 years** • **Allergic Rhinitis:** 60 mg twice daily, when required. • **Seasonal Allergic Rhinitis:** 120 mg or 180 mg once daily, when required. • **Urticaria:** 180 mg once daily, when required. The efficacy and safety of fexofenadine have not been established in children under 2 years of age for seasonal allergic rhinitis and under 6 months of age for urticaria. **Pediatric** • **Allergic rhinitis and seasonal allergic rhinitis** Children aged 2 to 11 years: 30 mg (5 ml of the suspension) twice daily, when required. • **Urticaria** Children aged 6 to 23 months: 15 mg (2.5 ml of the suspension) twice daily, when required. Children aged 2 to 11 years: 30 mg (5 ml of the suspension) twice daily, when required.
Dosage Adjustment	**Renal impairment** **Adults (Oral)** – eGFR ≥50 mL/minute/1.73 m^2, no dosage adjustment necessary. – eGFR 10 to <50 mL/minute/1.73 m^2: 60 mg every 12 to 24 hours. – eGFR <10 mL/minute/1.73 m^2: 60 mg every 24 hours. – Hemodialysis, intermittent (thrice weekly): Not dialyzable. Oral: 60 mg every 24 hours. – Peritoneal dialysis: Significant removal unlikely. Oral: 60 mg every 24 hours **Pediatric**

Fexofenadine

	– Infants ≥6 months to children <2 years: Any degree of kidney impairment: 15 mg once daily. – Children 2 to 11 years: Any degree of kidney impairment: 30 mg once daily. – Children ≥12 years and adolescents: Any degree of kidney impairment: 60 mg once daily. **Hepatic impairment** No dosage adjustment is needed.
Contra-indications	Hypersensitivity to the active substance.
Adverse Drug Reactions	**>10%** **Gastrointestinal:** Vomiting (infants and children: 12%). **1% to 10%** **Gastrointestinal:** Diarrhea (infants and children: 4%), stomach discomfort (adolescents and adults: 2%). **Genitourinary:** Dysmenorrhea (adolescents and adults: 2%). **Nervous system:** Dizziness (adolescents and adults: 2%), drowsiness (infants and children: ≤3%), fatigue (infants and children: ≤3%), headache (adolescents and adults: 5% to 10%). **Neuromuscular and skeletal:** Back pain (adolescents and adults: 2% to 3%), limb pain (adolescents and adults: 2%). **Respiratory:** Cough (children: 4%), rhinorrhea (infants and children: 2%), upper respiratory tract infection (children: 3%). **Miscellaneous:** Fever (children: 2%).
Monitoring Parameters	Relief of symptoms.
Drug Interactions	***Risk X: Avoid combination*** Pitolisant. ***Risk D: Consider Therapy Modification*** Antacids, Benzylpenicilloyl Polylysine.
Pregnancy and Lactation	**Pregnancy** Fexofenadine hydrochloride should not be used during pregnancy unless clearly necessary. **Lactation** Fexofenadine hydrochloride is not recommended for mothers breastfeeding their babies.
Administration	• **Tablets:** Should be administered before meals. • **Oral suspension:** Shake suspension well before use. **N.B.** Refer to the manufacturer's PIL for specific considerations.
Warnings/ Precautions	• Use with caution in patients with renal impairment. • Use with caution in elderly patients. • Patients with a history of or ongoing cardiovascular disease should be warned that antihistamines, as a class of medicines, have been associated with adverse

Fexofenadine

	reactions, such as tachycardia and palpitation.
Storage	Store at 20°C to 25°C. **N.B.** Refer to the manufacturer's PIL for specific considerations.

Loratadine

Generic Name	Loratadine
Dosage Form/Strengths	**Chewable tablets**: 5 mg, 10 mg. **Orally disintegrating tablets:** 10 mg. **Tablets**: 10 mg. **Oral syrup**: 2.5 mg/5ml, 1 mg/ml.
Route of Administration	Oral
Pharmacologic Category	Histamine H_1 antagonist, second generation; piperidine derivative. **ATC:** R06AX13
Indications	Symptomatic treatment of allergic rhinitis and chronic idiopathic urticaria in adults and children over the age of 2 years.
Dosage Regimen	**Allergic rhinitis and chronic idiopathic urticaria** - **Adults and children over 6 years of age**: 10 mg once daily. - **Pediatric age 2 to 6 years:** 5 mg once daily. **Alternative dosing for children <12 years of age** (based on body weight) Body weight ≤ 30 kg: 5 mg once daily. Body weight >30 kg: 10 mg once daily. - **Children under 2 years of age:** Safety and efficacy have not been established. No data are available.
Dosage Adjustment	**Renal impairment** CrCl ≥30 mL/minute: No dosage adjustment necessary. CrCl <30 mL/minute: 10 mg every 48 hours. **Hepatic impairment** • **Mild or moderate liver impairment:** No dosage adjustment necessary. • **Severe liver impairment** - Adults and children weighing more than 30 kg: Initial: 10 mg every other day. - Children weighing 30 kg or less: 5 mg every other day is recommended.
Contra-indications	Hypersensitivity to the active substance or to any of the excipients.
Adverse Drug Reactions	**>10%** **Nervous system:** Headache (adolescents and adults: 12%) **1% to 10%** **Cardiovascular:** Chest pain (<2%), flushing (<2%), hypertension (<2%), hypotension (<2%), palpitations (<2%), supraventricular tachycardia (<2%), syncope (<2%), tachycardia (<2%). **Dermatologic:** Dermatitis (<2%), diaphoresis (<2%), dry hair (<2%), pruritus (<2%), skin photosensitivity (<2%), skin rash (children: 2% to 3%), xeroderma (<2%). **Endocrine and metabolic:** Decreased libido (<2%), heavy menstrual bleeding

Loratadine

	(<2%), increased thirst (<2%), weight gain (<2%). **Gastrointestinal:** Abdominal pain (children: 2%), altered salivation (<2%), anorexia (<2%), constipation (<2%), diarrhea (children: 2% to 3%), dysgeusia (<2%), dyspepsia (<2%), flatulence (<2%), gastritis (<2%), hiccups (<2%), increased appetite (<2%), loose stools (<2%), nausea (<2%), stomatitis (children: 2% to 3%), vomiting (<2%), xerostomia (adolescents and adults: 3%). **Genitourinary:** Altered micturition (<2%), dysmenorrhea (<2%), impotence (<2%), mastalgia (<2%), urinary incontinence (<2%), urinary retention (<2%), urine discoloration (<2%), vaginitis (<2%). **Hematologic and oncologic:** Purpuric disease (<2%) **Hypersensitivity:** Angioedema (<2%) **Infection:** Viral infection (children: 2% to 3%) **Nervous system:** Agitation (<2%), amnesia (<2%), anxiety (<2%), confusion (<2%), depression (<2%), dizziness (<2%), drowsiness (adolescents and adults: 8%), fatigue (2% to 4%), hypertonia (<2%), hypoesthesia (<2%), insomnia (<2%), irritability (<2%), lack of concentration (<2%), malaise (children: 2%), migraine (<2%), nervousness (children: 4%), nightmares (<2%), paresthesia (<2%), rigors (<2%), vertigo (<2%), voice disorder (children: 2%). **Neuromuscular and skeletal:** Arthralgia (<2%), asthenia (<2%), back pain (<2%), hyperkinetic muscle activity (children: 3%), lower limb cramp (<2%), myalgia (<2%), tremor (<2%). **Ophthalmic:** Blepharospasm (<2%), blurred vision (<2%), conjunctivitis (children: 2%), eye pain (<2%). **Otic:** Otalgia (children: 2% to 3%), tinnitus (<2%). **Respiratory:** Bronchitis (<2%), bronchospasm (<2%), cough (<2%), dry nose (<2%), dyspnea (<2%), epistaxis (children: 2% to 3%), flu-like symptoms (children: 2% to 3%), hemoptysis (<2%), laryngitis (<2%), pharyngitis (children: 2% to 3%), upper respiratory tract infection (children: 2%), wheezing (children: 4%). **Miscellaneous:** Fever (<2%)
Monitoring Parameters	There are no monitoring parameters needed.
Drug Interactions	***Risk X: Avoid combination*** Pitolisant. ***Risk D: Consider Therapy Modification*** Amiodarone, Benzylpenicilloyl Polylysine.
Pregnancy and Lactation	**Pregnancy** No malformities or neonatal toxicity have been shown in human studies. However, it is preferable to avoid the use of loratadine during pregnancy. **Lactation** Loratadine is excreted in breast milk; therefore, its use is not recommended in breastfeeding women.
Administration	**Oral administration** Dose may be taken without regard to meal time.

Loratadine

	• **Orally disintegrating tablets:** The tablet shall be put on the tongue, and the patient should wait until it is thoroughly disintegrated and dissolved. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	**Allergy skin test** Loratadine should be discontinued at least 48 hours before skin tests. Antihistamines may prevent or reduce positive reactions to the dermal reactivity index. **Severe liver impairment** Loratadine should be administered with caution in patients with severe liver impairment. **Drowsiness** Very rarely, some people experience drowsiness, which may affect their ability to drive or use machines.
Storage	Store below 30 °C. Protect tablets from moisture. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Anti-Muscarinic Agents

Ipratropium Bromide

Generic Name	Ipratropium Bromide
Dosage Form/Strengths	**Nebulizer solution for inhalation:** 250 mcg /ml, 500 mcg /2ml, 250 mcg /2ml.
Route of Administration	*Oral Inhalation*
Pharmacologic Category	*Anticholinergic agent* **ATC**: *R03BB01*
Indications	***Nebulization*** • For the treatment of reversible airway obstruction associated with chronic obstructive pulmonary disease (COPD). • When used concomitantly with inhaled beta2-agonists, for treatment of reversible airways obstruction as in acute and chronic asthma.
Dosage Regimen	**Adults, the elderly, and children over 12 years of age** • ***Acute therapy:*** *500 mcg;* the time interval between the doses must be determined by the physician. • ***Maintenance therapy:*** 250 - 500 micrograms 3 to 4 times daily. • Daily doses exceeding 2 mg in adults and children over 12 years of age should only be given under medical supervision. **Pediatric dosing** ***Acute therapy*** • **6-12 years of age:** 250 micrograms up to a total daily dose of 1mg. The physician may determine the time interval between doses. • **< 6 years of age (for treatment of acute asthma only):** 125 – 250 micrograms up to a total daily dose of 1 mg. No more frequently than 6 hours. ***Maintenance therapy*** • **Children < 12 years of age:** As only limited information is available, the following dose schedule should only be given under regular medical supervision: 250 mcg 3 - 4 times daily.
Dosage Adjustment	**Renal impairment** No dose adjustments needed (has not been studied). **Hepatic impairment** No dose adjustments needed (has not been studied).
Contra-indications	• Hypersensitivity to ipratropium, atropine, or any of the excipients.
Adverse Drug Reactions	**10%** **Respiratory**: Bronchitis (10 - 23%), exacerbation of chronic obstructive pulmonary disease (8 - 23%), sinusitis (1 - 11%). **1% to 10%**

Ipratropium Bromide

	Central nervous system: Headache (6 - 7%), dizziness (3%). **Gastrointestinal**: Dyspepsia (1 - 5%), nausea (4%), xerostomia (2 - 4%), dysgeusia (1%). **Genitourinary**: Urinary tract infection (2 - 10%). **Neuromuscular and skeletal**: Back pain (2 - 7%). **Respiratory**: Dyspnea (7 - 8%), flu-like symptoms (4 - 8%), cough (>3%), rhinitis (>3%), upper respiratory tract infection (>3%).
Monitoring Parameters	Monitor for symptoms of bronchospasm, hypersensitivity reactions, urinary retention, or glaucoma.
Drug Interactions	***Risk X: Avoid combination*** Anticholinergic Agents, Loxapine. ***Risk D: Consider therapy modification*** Methacholine.
Pregnancy and Lactation	**Pregnancy** • No human data. • Only to be administered during pregnancy if the possible benefit outweighs the potential risk to the fetus. **Lactation** • No human data. • It is unlikely that ipratropium would reach the infant to an important extent; however, caution should be exercised when administered to nursing mothers.
Administration	**Nebulization solution** • Sterile sodium chloride 0.9% can be used for dilution if required. • After use, throw away any remaining solution and clean the nebulizer. **N.B.** Refer to the manufacturer's PIL if there are specific considerations.

Ipratropium Bromide

Warnings/ Precautions	***Adverse effects related issues*** • **Anaphylaxis and other hypersensitivity reactions:** If symptoms develop (e.g., urticaria, angioedema, rash, bronchospasm, oropharyngeal edema, and anaphylaxis), discontinue immediately and consider alternatives. • **Paradoxical bronchospasm:** It may develop in some cases. If it occurs, the drug should be discontinued immediately, and this should be treated with a fast-acting inhaled bronchodilator. • **CNS effects:** May cause dizziness and blurred vision; patients must be cautioned about performing tasks that require mental alertness (e.g., operating machinery or driving). ***Disease-related issues*** • **Glaucoma:** Use with caution, as if ipratropium has come into contact with the eyes during nebulization, it may cause mydriasis, increased intraocular pressure, narrow-angle glaucoma, and eye pain. If this occurs, treatment with miotic drops should be initiated, and specialist advice should be sought immediately. • **Prostatic hypertrophy:** Use with caution as it may increase urinary retention. • **Cystic fibrosis:** Use with caution, as due to anticholinergic effects, gastrointestinal motility abnormalities may occur. ***Other warnings/precautions*** • **Appropriate use:** Not indicated for the initial treatment of acute episodes of bronchospasm where rescue therapy is required for rapid response. Only use in acute exacerbations of asthma in conjunction with short-acting beta-adrenergic agonists for acute episodes.
Storage	• Store below 25°C. • The ampoule should be opened immediately before use, and any solution remaining after use should be discarded. **N.B.** Refer to the manufacturer's PIL if there are specific considerations.

Tiotropium

Generic Name	Tiotropium
Dosage Form/ Strengths	Dry powder in hard capsule: 18 mcg
Route of Administration	Oral Inhalation
Pharmacologic Category	Anticholinergic agent, long-acting bronchodilators **ATC:** R03BB04.
Indications	• Maintenance broncho dilator treatment of bronchospasm in patients with chronic obstructive pulmonary disease (COPD). • Reduction of COPD exacerbations.
Dosage Regimen	**Adults and geriatric dosing** Two inhalations of the powder contents of a single capsule (18 mcg) once daily using the device at the same time of the day. **Pediatric dosing** There is no relevant use in the pediatric population (below 18 years) in the COPD indication.
Dosage Adjustment	**Renal impairment** • As plasma concentration increases with decreased renal function in patients with moderate to severe renal impairment (creatinine clearance ≤ 50 ml/min), tiotropium bromide should be used only if the expected benefit outweighs the potential risk. • There is no long-term experience in patients with severe renal impairment. • CrCl ≤60 mL/minute: No dosage adjustment necessary; use with caution and closely monitor for anticholinergic adverse events. **Hepatic impairment** • No dosage adjustments are needed.
Contra-indications	Hypersensitivity to atropine and its derivatives, ipratropium, tiotropium, or any component of the formulation.
Adverse Drug Reactions	**> 10%** **Gastrointestinal:** Xerostomia (4% to 16%) **Respiratory:** Pharyngitis (9% to 16%), sinusitis (3% to 11%), upper respiratory tract infection (41%) **1% to 10%** **Cardiovascular:** Angina pectoris (1% to 3%), chest pain (≤7%), edema, hypertension (1% to 2%), palpitations (≤3%) **Dermatologic:** Pruritus (1% to 3%), skin rash (1% to 4%). **Endocrine and metabolic:** Hypercholesterolemia, hyperglycemia (1% to 3%). **Gastrointestinal:** Abdominal pain 5%, constipation (1% to 5%), diarrhea (1% to 2%), dyspepsia (6%), gastroesophageal reflux disease (≤3%), oropharyngeal candidiasis (1% to 3%), stomatitis (1% to 3%), vomiting (4%). **Genitourinary:** Urinary tract infection (1% to 7%).

Tiotropium

	Hypersensitivity: Hypersensitivity reaction (≤3%). **Infection:** Candidiasis (4%), herpes zoster (≤3%), infection (4%). **Nervous system:** Depression (1% to 4%), dizziness (1% to 3%), headache (4% to 6%), insomnia (≤4%), paresthesia (1% to 3%), voice disorder (≤3%). **Neuromuscular and skeletal:** Arthralgia (≤4%), arthritis (≥3%), limb pain (≤3%), myalgia (4%), skeletal pain (1% to 3%). **Ophthalmic:** Cataract (1% to 3%). **Respiratory:** Allergic rhinitis (1% to 2%), bronchitis (3%), cough (≥1%), epistaxis (≤4%), flu-like symptoms (≥3%), laryngitis (≤3%), rhinitis (≤6%) **Miscellaneous:** Fever (1% to 2%).
Monitoring Parameters	• Patients with a history of hypersensitivity reactions to atropine or its derivatives should be closely monitored for similar hypersensitivity reactions to tiotropium. • Immediate hypersensitivity reactions: Discontinue tiotropium at once and consider alternatives if immediate hypersensitivity reactions, including angioedema, urticaria, rash, bronchospasm, or anaphylaxis, occur. Use with caution in patients with severe hypersensitivity to milk proteins. • Inhalation-induced bronchospasm. • Pulmonary function, FEV1, and peak flow. • Anticholinergic adverse reactions. • Patients with moderate to severe renal impairment (creatinine clearance of <60 mL/min) treated with tiotropium should be monitored closely for anticholinergic side effects. • Signs and symptoms of narrow-angle glaucoma include eye pain or discomfort, blurred vision, visual halos, or colored images in association with red eyes from conjunctival congestion and corneal edema. • Signs and symptoms of prostatic hyperplasia or bladder-neck obstruction and urinary retention.
Drug Interactions	***Risk X: Avoid combination*** Aclidinium, Anticholinergic Agents, Cimetropium, dronabinol, Eluxadoline, Glycopyrrolate (Oral Inhalation), Glycopyrronium (Topical), Ipratropium (Oral Inhalation), Levosulpiride, Loxapine, Oxatomide, Potassium Chloride, Potassium Citrate, Pramlintide, Revefenacin, Sofpironium, Umeclidinium. ***Risk D: Consider therapy modification*** Methacholine, Rivastigmine, Secretin.
Pregnancy and Lactation	**Pregnancy** • There is limited data; the healthcare provider should evaluate the risk of pregnant mother exposure versus the benefits of treatment to the mother, and should use it during pregnancy only if the potential benefit justifies the potential risk to the fetus. • As a precautionary measure, it is preferable to avoid the use of tiotropium during pregnancy. **Lactation** • There is limited data about the use of tiotropium during breastfeeding.

Tiotropium

	• The healthcare provider should evaluate the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother. • Caution should be exercised if tiotropium is administered to a nursing woman.
Administration	**Administration: Oral inhalation** **Dry powder in a hard capsule** • The patient should remove the capsule from the blister to use immediately, then place the capsule in the center chamber of the holding inhaler. The patient should make sure that the mouthpiece is clear and has been firmly closed, and hear a click when leaving the dust cap open. The patient should pierce the capsule by pressing and releasing the green piercing button on the side of the holding device. • The previous process, called priming and piercing, should not be repeated more than once. • The patient exhales fully, then closes the lips tightly around the mouthpiece. The patient should not exhale into the inhaler after putting it in the mouth. • The patient tilted their head slightly back and inhaled rapidly, steadily, and deeply, to let the powder release from the capsule through hearing the voice of rattling (capsule vibration). • The patient holds breath for a few seconds, then repeats the inhalation procedure using the same tiotropium capsule without piercing the capsule a second time (without priming), to ensure full drug delivery. • After receiving the dose, the patient should open the device and throw away the empty capsule by tipping it into a trash can without touching it; it should not be left in the inhaler. • The capsules and inhaler should be kept dry at a temperature not exceeding 25 °C. • Discard any capsules that are exposed to air and not used immediately. • The patient should not swallow the capsule or use it through the nose, and preferred to administer at the same time each day. **N.B.** Refer to the manufacturer's PIL for specific considerations.
Warnings/ Precautions	• No data for use in children or adolescents < 18 years. • Capsules taken only by inhalation. • Tiotropium should be discontinued and consider other therapy if: - Immediate hypersensitivity reactions occur, e.g., urticaria, angioedema, rash, bronchospasm, anaphylaxis, and itching. - Paradoxical bronchospasm occurs. • Tiotropium should not be used for the treatment of acute bronchospasm or as rescue therapy. • The patient should be aware and avoid touching or reaching powder in the eyes. • May cause dizziness and blurred vision; patients must be cautioned about performing tasks that require mental alertness, e.g., operating machinery or driving.

Tiotropium

	• May cause dental caries as a result of long-term anti-cholinergic dry mouth effect. • Use with caution in patients with: - Narrow-angle glaucoma may worsen symptoms. - Prostatic hyperplasia/bladder neck obstruction may worsen the symptoms. - Moderate to severe renal impairment. - A history of hypersensitivity to atropine. - Recent myocardial infarction < 6 months. - Any unstable or life-threatening cardiac arrhythmia.
Storage	• Store at 25°C. • Avoid freezing, extreme temperatures, and moisture. • Do not store capsules in the device; store capsules in the blister pack and only remove immediately before use. • Once the protective foil is peeled back and/or removed, the capsule should be used immediately; if the capsule is not used immediately, it should be discarded. **N.B.** Refer to the manufacturer's PIL if there are specific considerations.

Anti-Tussive Agents (Cough Suppressants)

Dextromethorphan

Generic Name	Dextromethorphan
Dosage Form/ Strengths	**Syrup**: 200 mg/100ml **Powder for oral solution:** 10 mg/5 g powder **Oral drops**: 10 mg/ml, 15 mg/ml **Tablets**: 10 mg, 15 mg
Route of Administration	Oral
Pharmacologic Category	Antitussive; N-Methyl-D-Aspartate (NMDA) Receptor Antagonist **ATC:** R05DA09
Indications	Cough suppressant for the relief of acute non-productive (dry, irritant) cough.
Dosage Regimen	**Dosing for adults and children aged 12 years and over** **Oral**: 10 mg-20 mg every 4-6 hours. Maximum dose: 80 mg/day. **Children under 12 years** **Tablets:** Dextromethorphan is contraindicated. **Syrup:** ▪ The medicine is contraindicated in children under 6 years of age. Child 6 to 12 years: One 5 ml spoonful, up to four times daily. ▪ Children of 6-12 years of age: Not to be used for more than 5 days without the advice of a doctor.
Dosage Adjustment	**Renal Impairment** Not studied. Caution in severe renal impairment. **Hepatic Impairment** Not studied. Caution. Do not exceed the stated dose.
Contra-indications	• Hypersensitivity to the active substance or any of the excipients. • Patient with, or at risk of developing, respiratory failure. • Patients taking monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment. • Patients taking selective serotonin reuptake inhibitors (SSRI). It shouldn't be used in children under 6 years old.
Adverse Drug Reactions	**Frequency not defined** **Central nervous system**: Dizziness, drowsiness, nervousness, restlessness, drug dependence, drug withdrawal syndrome. **Gastrointestinal**: Gastrointestinal distress, nausea, stomach pain, vomiting. **Miscellaneous**: Hypersensitivity.
Monitoring Parameters	Monitor for side effects.
Drug Interactions	***Risk X: Avoid combination*** Disulfiram, Mavorixafor, Methotrimeprazine, Metronidazole (Systemic), Monoamine Oxidase Inhibitors, Secnidazole.

Dextromethorphan

	Risk D: Consider Therapy Modification Selective Serotonin Reuptake Inhibitors (Strong CYP2D6 Inhibitors).
Pregnancy and Lactation	**Pregnancy** No human data. Animal studies do not indicate embryofetal toxicity. Consider the potential benefit against any possible hazards before use. **Lactation** Dextromethorphan and its metabolite are excreted in breast milk in minor quantities. No data. Consider the potential benefit against any possible hazards before use.
Administration	Oral administration **N.B.** Refer to the manufacturer's PIL for specific considerations.
Warnings/ Precautions	**Respiratory disorders** • Patients with the following conditions should not use this product, unless directed by a physician: acute or chronic asthma, chronic cough such as in chronic bronchitis or emphysema, or where cough is accompanied by excessive secretions. • Patient should stop use and ask a healthcare professional if cough lasts more than 7 days, comes back, or is accompanied by a fever, rash, or persistent headache. These could be signs of serious conditions. **Poor metabolizers of CYP2D6** Due to that, dextromethorphan is metabolized by hepatic cytochrome P450 2D6; poor metabolizers and patients with concomitant use of CYP2D6 inhibitors may experience exaggerated or prolonged effects of dextromethorphan. Use with caution. **CNS effects** • Patients should be advised that they may experience effects such as drowsiness and dizziness during treatment. If these symptoms develop, the patient should avoid potentially hazardous tasks such as driving or operating machinery. • Dextromethorphan should not be taken with any other cough and cold medicines. Drinking alcohol should be avoided during treatment. **Drug dependence, tolerance, and potential for abuse** • Cases of dextromethorphan abuse and dependence have been reported. • Caution is particularly recommended for adolescents and young adults, as well as in patients with a history of drug abuse or psychoactive substances. • Prolonged use of dextromethorphan in all patients may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with a current or history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression). **Drug withdrawal syndrome** • It causes drug withdrawal syndrome, so healthcare providers should be alert to these problems. • Symptoms of drug withdrawal syndrome include: restlessness, lacrimation,

Dextromethorphan

	rhinorrhea, perspiration, chills, myalgia, mydriasis, and palpitations. Other symptoms may also develop, including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhea, increased blood pressure, increased respiratory rate, or heart rate. **Serotonin syndrome** • Dextromethorphan should not be taken with serotonergic agents because it may cause serotonin syndrome. If serotonin syndrome is suspected, treatment with dextromethorphan should be discontinued. • Serotonergic agents include selective serotonin reuptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including monoamine oxidase inhibitors (MAOIs)), and CYP2D6 inhibitors. • Serotonergic effects include mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. **Children** • Dextromethorphan should be used with caution in atopic children due to histamine release.
Storage	Store below 30°C. Protect solid forms from moisture. **N.B.** Refer to the manufacturer's PIL for specific considerations.

Beta2-Adrenoceptor Agonists

Formoterol

Generic Name	Formoterol
Dosage Form/ Strengths	**Inhalation powder in a hard capsule** • 12 mcg alone • 12 mcg in combination with 400 mcg budesonide • 6 mcg in combination with 200 mcg budesonide **Inhalation powder** • 4.5 mcg (in combination with 80 mcg budesonide) • 4.5 mcg (in combination with 160 mcg budesonide) • 9 mcg (in combination with 320 mcg budesonide) **Pressurized Inhalation Solution** • 12 mcg alone • 6 mcg in combination with 100 beclomethasone dipropionate • 5 mcg in combination with fluticasone propionate 50 mcg • 5 mcg in combination with fluticasone propionate 100 mcg • 10 mcg in combination with fluticasone propionate 250 mcg **Oral Inhalation** 5 mcg formoterol fumarate dihydrate micronized + 4.5 mcg formoterol fumarate in combination with 160 mcg budesonide + 9 mcg glycopyrroium bromide
Route of Administration	Oral Inhalation
Pharmacologic Category	Beta2 agonist; beta2-adrenergic agonist, long-acting **ATC:** R03AC13
Indications	• Indicated for use in the treatment and prophylaxis of bronchoconstriction in patients with asthma treated with inhaled corticosteroids and who also require a long-acting beta2-agonist in accordance with current treatment guidelines. • Indicated also for the treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), such as chronic bronchitis and emphysema. • For children from 6 years and above: for treatment and prophylaxis of bronchoconstriction in patients with asthma. Prophylaxis of acute attacks of bronchoconstriction, including those triggered by allergens, exercise, or cold air. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Regimen	**Adult dosing** **Maintenance of COPD** • Oral inhalation: 1 inhalation (12 micrograms) to be inhaled once or twice daily**,** • The daily dose for regular use should not exceed 2 inhalations. • Extra inhalations beyond those recommended for routine therapy may be used if necessary to relieve symptoms, up to a maximum daily dosage of four inhalations (regular plus as needed). It is not recommended to take more than 2 breaths in a single sitting.

Formoterol

	Asthma (adjunctive therapy, not as monotherapy) • Oral inhalation: 1 to 2 inhalations (12 micrograms to 24 mcg) every 12 hours according to severity. • The daily dose for regular use should not exceed 4 inhalations; however, occasionally up to a maximum of 6 inhalations may be allowed within 24 hours. N.B. It is not recommended to take more than 2 breaths in a single sitting. **EIB (Exercise Induced Bronchospasm)** • Oral inhalation: 1 inhalation (12 mcg) 15 minutes before exercise. **Geriatric dosing** Refer to adult dosing. **Pediatric dosing** Children from 6 to < 12 years, oral inhalation for: • Asthma: 12 mcg every 12 hours; the maximum dose is 24 mcg per day, in combination with inhaled corticosteroids. Formoterol as a single drug should not be used to relieve acute symptoms of an asthma attack; a short-acting beta 2 agonist should be used. As a relief medication: 1 inhalation for the relief of acute broncho-obstructive symptoms. • Chronic obstructive pulmonary disease is not appropriate. • EIB: 12 mcg 15 minutes before exercise, on an occasional, as-needed basis. No additional doses for 12 hours after. Children > 12 years and adolescents, oral inhalation for: • Asthma: Refer to adult dosing. • Maintenance of COPD: Refer to adult dosing. • EIB: Refer to adult dosing. - **N.B.** The regular daily dose in children and adolescents 6 years and older should not exceed 2 inhalations; however, occasionally up to a maximum of 4 inhalations may be allowed within 24 hours. No more than 1 inhalation should be taken on any single occasion. - Formoterol is **not** recommended for use in children under the age of 6 years due to insufficient data on safety and efficacy. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Adjustment	**Renal impairment** There is data available for use in renal impairment (not studied). **Hepatic impairment** There is data available for use in hepatic impairment (not studied). **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**

Formoterol

Contra-indications	Hypersensitivity to the active substance formoterol or any component of the formulation. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Adverse Drug Reactions	**1% to 10%** **Cardiovascular:** Chest pain (2% to 3%) **Central nervous system:** Anxiety (2%), dizziness (2%), insomnia (2%), voice disorder (1%), headache **Dermatologic:** Pruritus (2%), skin rash (1%) **Gastrointestinal:** Diarrhea (5%), nausea (5%), xerostomia (1% to 3%), vomiting (2%), abdominal pain, dyspepsia, gastroenteritis **Neuromuscular and skeletal:** Muscle cramps (2%), tremor **Respiratory:** Respiratory tract infection (3% to 7%), exacerbation of asthma (ages 5 to 12 years: 5% to 6%; age >12 years: <4%; acute deterioration: <1%), bronchitis (5%), pharyngitis (3% to 4%), sinusitis (3%), dyspnea (2%), tonsillitis (1%) **Miscellaneous:** Fever (2%) **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Monitoring Parameters	Forced Expiratory Volume in 1 second (FEV1), peak flow, and/or other pulmonary function tests; shortness of breath; blood pressure, heart rate; CNS stimulation; serum glucose, serum potassium. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Drug Interactions	***Risk X: Avoid combination*** Beta2-Agonists (Long-Acting), Beta-Blockers (Nonselective), Kratom, Loxapine. ***Risk D: Consider therapy modification*** Cocaine (Topical), Linezolid, Methacholine. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Pregnancy and Lactation	**Pregnancy** • There are no adequate data from the use of formoterol in pregnant women. • Treatment with formoterol may be considered at all stages of pregnancy if needed to obtain asthma control, and if the expected benefit to the mother is greater than any possible risk. **Lactation** • There is limited information on whether formoterol is present in breast milk. • Breastfeeding women should not use formoterol. It has been detected in animal milk. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Administration	N.B. The patient should administer it at the same time each day. **Dry powder in a hard capsule. See the accompanying patient instructions for use.**

Formoterol

- The patient should remove the capsule from the blister to use immediately, then place the capsule in the center chamber of the holding inhaler.
- The patient should make sure that the mouthpiece has been firmly closed and hear a click when leaving the dust cap open.
- The patient should pierce the capsule by pressing and releasing the piercing button on the side of the holding device. The previous process, called priming and piercing, should not be repeated.
- The patient exhales fully, then closes the lips tightly around the mouthpiece.
- The patient should not exhale into the inhaler after putting it in the mouth.
- The patient tilts his head slightly back and inhales rapidly, steadily, and deeply, to let the powder release from the capsule through hearing of rattling (capsule vibration).
- The patient holds breath for a few seconds, then repeats the inhalation procedure using the same capsule without piercing the capsule a second time (without priming), to ensure full drug delivery.
- After receiving the dose, the patient should open the device and throw away the empty capsule by tipping it into a trash can without touching it; it should not be left in the inhaler.
- The capsules and inhaler should be kept dry.
- Discard any capsules that are exposed to air and not used immediately.
- The patient should not swallow the capsule or use it through the nose.
- If the mouthpiece needs cleaning, it should be wiped with a dry cloth or a small soft brush.

Pressurized inhalation solution

- The patient should hold the pressurized inhaler that contains full doses, move the inhaler cover, and shake the inhaler, which means a dose is ready to use through a small hole (mouthpiece).
- Before the first use of the inhaler and after 3 days or more of non-use, one, two, or three actuations should be discharged in the air.
- The previous process is called priming. The patient should hold the device upwards, and be ready to press down the can.
- For patients with weak hand-grip, it could be easier to hold the inhaler with both hands.
- The patient exhales fully, then closes the lips tightly around the mouthpiece. The patient should not exhale while putting the inhaler in the mouth.
- The patient should sit and tilt his head slightly back, ready for a coordination between pressing down for actuation and inhaling the vapor (puff) out slowly, steadily, and deeply at the same time.
- The use of a spacer device with the inhaler is usually recommended for patients who have difficulty coordinating inhalation with actuation.
- The patient cannot stop inhaling or press a second press on the inhaler in the mouth.
- After receiving the dose, the patient should move the device and hold breath for 10 seconds, then breathe out slowly away from the device.
- In case of a need for a second puff, the patient should start the process one minute after the first puff.

Formoterol

	- To close the device, the patient returns the cover of the canister. - There is a counter to check the number of doses the patient still has. Once the number reaches zero, that means no longer having doses inside the disk - For cleaning, the patient should remove the metal canister from the plastic body of the inhaler and wipe the mouthpiece with water or tissue, then dry and replace the canister, and never use water with the metal canister. **N.B.** Refer to the manufacturer's PIL if there are specific considerations.
Warnings/ Precautions	**Disease-related concerns** **• Asthma** -Patients should not be initiated on formoterol during an acute severe asthma exacerbation or if they have significantly worsened or acutely deteriorating asthma. - Patients should also receive optimal maintenance anti-inflammatory therapy with corticosteroids. Serious asthma-related adverse events and exacerbations may occur during treatment with formoterol alone. **• Cardiovascular disease** -Use with caution in patients with cardiovascular disease (arrhythmia, coronary insufficiency, or hypertension); beta-agonists may cause elevation in blood pressure and heart rate and result in CNS stimulation/excitation. - Beta-2 agonists have been reported to produce ECG changes, such as flattening of the T wave, prolongation of the QTc interval, and ST segment depression. **• Diabetic patients** -Due to the hyperglycemic effects of β2-agonists, additional blood glucose monitoring is recommended initially in diabetic patients. **• Bronchospasm** -The potential for paradoxical bronchospasm should be considered. If it occurs, the treatment should be discontinued immediately, and alternative therapy started **• Hypokalemia** -Potentially serious hypokalemia may result from Beta 2-agonist therapy. -Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia. **• Hyperthyroidism** - Use with caution in hyperthyroidism; may stimulate thyroid activity. **• Pediatric population** - Children under 6 years should not be treated with formoterol, as no sufficient experience is available for this group. - LABAs, when used as monotherapy, may increase the risk of asthma-related hospitalization in pediatric and adolescent patients. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Storage	**Capsule** • Store at temperature not exceed 30°C in a dry place. • Do not store capsules in the device; store capsules in the blister pack and only remove immediately before use.

Formoterol

	• Store in the original container to protect from moisture. **Pressurized Inhalation Solution** • The product should be stored at a temperature between 2°C and 8°C, for a period up to 15 months. • When used by the patient, the product should be stored at a temperature not exceeding 30°C for a maximum of three months. **N.B**. Refer to the manufacturer's PIL for specific considerations.

Salbutamol

Generic Name	Salbutamol
Dosage Form/Strengths	**Sustained release capsule (SR):** 4 mg, 8 mg **Tablet**: 2 mg, 4 mg (1mg in combination with 4 mg bromhexine hydrochloride) **Syrup** • 2 mg/5 ml • 2 mg + 50 mg guaifenesin /5ml • 2 mg + 100 mg ammonium chloride /5ml • 1 mg + 50 mg guaifenesin + 2 mg bromhexine chloride /5ml **Oral inhalation solution** • 5 mg/ml, 2.5 mg/2.5ml, 5 mg/2.5ml • 2.5 mg + 0.5 mg ipratropium bromide /2.5ml • 1 mg + 0.2 mg ipratropium bromide / 1 ml **Oral dry powder inhalation:** 200 mcg/dose **Oral metered dose inhaler** • 0.1 mg/dose • 0.1 mg + 0.02 mg ipratropium chloride/dose • 0.1 mg + 0.05 mg beclomethasone dipropionate /dose **Parenteral SC/IM/IV:** 0.5 mg/ml
Route of Administration	Oral, Oral Inhalation, Parenteral
Pharmacologic Category	Selective Beta2 Agonist, short-acting **ATC** Oral Inhalation: R03AC02 Oral, Parenteral: R03CC02
Indications	• For the relief of bronchospasm in bronchial asthma of all types • Chronic bronchitis • Emphysema • **IV form**: For the short-term management of uncomplicated premature labour. To arrest labour between 22 and 37 weeks of gestation in patients with no medical or obstetric contraindication to tocolytic therapy.
Dosage Regimen	**Adult Dosing** • **Oral tablets**: 4 mg 3–4 times a day, maximum single dose 8 mg. For elderly or in those known to be unusually sensitive to beta-adrenergic stimulant drugs: Initially 2 mg 3–4 times a day, maximum single dose 8 mg. • **Oral syrup**: The minimum starting dose is 2 mg every 6-8 hours per day. The usual dose is 4 mg every 8-6 hours per day; the maximum dose is 8 mg. • **Oral inhalation**, one inhalation (100 mcg) or two inhalations up to 4 times a day for persistent symptoms. The maximum daily dose should not exceed 8 inhalations and should usually not be repeated more often than every 4 hours. • **Nebulization** solution: 2.5–5 mg up to 4 times daily or more in severe cases, the maximum dose up to 40 mg per day under medical supervision in a hospital.

Salbutamol

	▪ **SC/IM injection**: 500 mcg (0.5mg) in 1ml every 4 hours or (8 mcg/kg bodyweight) every 4 hours as required. ▪ **IV injection**: 250 micrograms or (4 mcg/kg bodyweight) injected slowly. If necessary, the dose may be repeated, to be diluted to a concentration of 50 micrograms/mL. Repeated, if necessary. ▪ **IV infusion**: 50 mcg (0.5mg) diluted in 50 ml of N.S 0.9% or D5W by usual dose 3–20 mcg/minute, higher doses may be used if needed with monitoring heart rate. **Pediatric dosing** **Oral: Tablet or oral syrup** 2-6 years: 1-2 mg three or four times daily 6-12 years: 2 mg three or four times daily Over 12 years: 2-4 mg three or four times daily **Oral inhalation** Children <12 years: one inhalation (100 mcg) or two inhalations up to 4 times daily. The maximum daily dose should not exceed 800 mcg, and should not exceed 6 times in 24 hours. **Nebulization** dose is 2.5 mg to 5 mg up to four times a day. Children > 12 years; the dose is as per the adult population. Children < 4 years: Other pharmaceutical forms may be more appropriate **Injection** The safety and efficacy of salbutamol Injection in children < 12 years have not been established. From the available data, no recommendation can be made.
Dosage Adjustment	**Renal Impairment** There are no dosage adjustments available. **Hepatic Impairment** There are no dosage adjustments available.
Contra-indications	• Hypersensitivity to salbutamol or any component of the formulations. • Non-I.V. formulations of salbutamol should not be used to stop uncomplicated premature labour or threatened abortion. • **I.V. infusion is contraindicated in the following conditions** – Any condition at a gestational age of < 22 weeks – As a tocolytic agent in patients with pre-existing ischaemic heart disease or those patients with significant risk factors for ischaemic heart disease. – Threatened abortion during the first and second trimester – Any condition of the mother or foetus in which prolongation of the pregnancy is hazardous, e.g., severe toxaemia, intrauterine infection, vaginal bleeding resulting from placenta praevia, eclampsia or severe preeclampsia, placental abruption, or cord compression. – Intrauterine foetal death, known lethal congenital or lethal chromosomal malformation. – Pulmonary hypertension and cardiac disorders such as hypertrophic obstructive cardiomyopathy or any type of obstruction of the left ventricular outflow tract, e.g., aortic stenosis.

Salbutamol

Adverse Drug Reactions	**>10%** **Nervous system:** Excitement (children, adolescents: 2% to 20%), nervousness (4% to 15%), tremor (5% to 38%) **Respiratory:** Bronchospasm (8% to 15%; exacerbation of underlying pulmonary disease), exacerbation of asthma (11% to 13%), pharyngitis (14%), rhinitis (5% to 16%), upper respiratory tract infection (5% to 21%) **1% to 10%** **Cardiovascular:** Chest pain (<3%), edema (<3%), extrasystoles (<3%), hypertension (1% to 3%), tachycardia (1% to 7%) (table 1) **Dermatologic:** Diaphoresis (<3%), pallor (children: 1%), skin rash (<3%), urticaria (≤2%) **Endocrine and metabolic:** Diabetes mellitus (<3%) **Gastrointestinal:** Anorexia (children: 1%), diarrhea (<3%), dyspepsia (1% to 2%), eructation (<3%), flatulence (<3%), gastroenteritis (3%), glossitis (<3%), increased appetite (children, adolescents: 3%), nausea (2% to 10%), unpleasant taste (inhalation site: 4%), viral gastroenteritis (1% to 3%), vomiting (3% to 7%), xerostomia (<3%) **Genitourinary:** Urinary tract infection (≤3%) **Hematologic and oncologic:** Lymphadenopathy (3%) **Hypersensitivity:** Hypersensitivity reaction (3% to 6%) **Infection:** Infection (<3%; skin/appendage: ≤2%) **Local:** Application-site reaction (HFA inhaler: 6%) **Nervous system:** Anxiety (<3%), ataxia (<3%), depression (<3%), dizziness (<7%), drowsiness (<3%), emotional lability (1%), fatigue (1%), headache (3% to 7%), hyperactive behavior (children, adolescents: 2%), insomnia (1% to 3%), malaise (2%), migraine (≤2%), pain (2%), rigors (<3%), shakiness (children, adolescents: 9%), vertigo, voice disorder (<3%) **Neuromuscular and skeletal:** Back pain (2% to 4%), hyperkinetic muscle activity (≤4%), lower limb cramp (<3%), musculoskeletal pain (3% to 5%) **Ophthalmic:** Conjunctivitis (children: 1%) **Otic:** Ear disease (<3%), otalgia (<3%), otitis media (≤4%), tinnitus (<3%) Respiratory: Bronchitis (≥2%), cold symptoms (3%), cough (≥3%), dyspnea (<3%), epistaxis (children, adolescents: 1%), flu-like symptoms (3%), increased bronchial secretions (2%), laryngitis (<3%), nasal congestion (1%), nasopharyngitis (≥5%; children: 2%), oropharyngeal edema (<3%), oropharyngeal pain (≥5%; children: 2%), pulmonary disease (<3%), respiratory system disorder (6%), sinus headache (1%), sinusitis (≥5%), throat irritation (10%), upper respiratory tract inflammation (5%), viral upper respiratory tract infection (7%), wheezing (1% to 2%) **Miscellaneous:** Accidental injury (<3%), fever (5% to 6%)
Monitoring Parameters	• Asthmatic patient response clinically and by lung function tests. • Blood pressure, heart rate, ECG. • Serum glucose, serum lactate, with particular regard to diabetic patients. • Serum potassium due to risk of hypokalemia.
Drug Interactions	***Risk X: Avoid combination*** Beta-Blockers (Nonselective), Kratom, Loxapine. ***Risk D: Consider therapy modification***

Salbutamol

	Beta2-Agonists (Short-Acting), Cocaine (Topical), Linezolid, Methacholine.
Pregnancy and Lactation	**Pregnancy** Salbutamol crosses the placenta; there is not enough data. It should only be considered if the expected benefit to the mother is greater than any possible risk to the fetus. **Lactation** Salbutamol is present in breast milk and should be restricted to situations where the expected benefit to the mother outweighs any potential risk to the neonate.
Administration	**Preparation** **IV:** Dilute 50 mcg (0.5 mg) in 50 ml of NS, D5W, or D5NS for a concentration of 10 mcg/mL, to be used within 24 hours. **Administration** **Oral:** Do not cut, crush, or chew ER tablets. **Dry powder inhalers (DPI)** • The patient should not wash or put any part of the inhaler in water, and clean it by wiping with a dry cloth or tissue. • The patient may need to activate or prime the dose depending on the device type or formula. • Before inhaling the dose, the patient should breathe out fully and should not exhale into the device. • The patient should seal the mouth and lips around the device mouthpiece and inhale steadily and deeply; then hold breath for about 10 seconds or for as long as comfortable and exhale slowly. • The patient should close the device and discard it when it counts 0. Use a spacer for children <5 years of age. **Metered-dose inhalers (MDI)** • The patient should shake well before use; and prime the dose especially before first use, and if it has not been used for >2 weeks by releasing 3 to 4 test sprays into the air (away from face). • Before inhaling the dose, the patient should breathe out fully and should not exhale into the device. • The patient should seal the mouth around the device mouthpiece and inhale slowly; then hold breath for about 10 seconds or for as long as comfortable and exhale slowly. • The patient should close the device and discard it when it counts 0. • Use a spacer for children <5 years of age. **Nebulizer Solution** • It is designed to be used undiluted. • However, if a prolonged delivery time (more than 10 minutes) is required, then dilution with sodium chloride solution (0.9%w/v) may be required. • The nebulizer flow is adjusted to deliver a dosage over 5 to 15 minutes.

Salbutamol

	• Avoiding contact of the multidose bottle tip with any surface is important, including the nebulizer reservoir and associated ventilator equipment. • In infants and children <4 years of age, a face mask with either the MDI or nebulizer is recommended. **N.B.** Refer to the manufacturer's PIL for specific considerations
Warnings/ Precautions	• Nebulizing solution should not be injected or swallowed. • Beta-2 agonists may decrease serum potassium; patients' serum potassium levels should be monitored. • Patients could receive different dosage forms of short-acting inhaled bronchodilators to relieve symptoms. • Salbutamol should be administered **cautiously** to patients with: - Suffering from thyrotoxicosis. - Receiving large doses of other sympathomimetics. - Cardiovascular disease (arrhythmia, coronary insufficiency, hypertension, heart failure), as it may either cause direct myocardial toxicity or exacerbate underlying myocardial dysfunction. - Diabetic patients, as it may increase serum glucose and aggravate preexisting diabetes and ketoacidosis. - Glaucoma may elevate intraocular pressure. - Renal impairment - Seizures, as it may result in CNS stimulation/excitation. - Milk protein allergy, as some inhalers may contain lactose • The patient should not exceed the recommended dose, as the need to increase frequency of use may indicate deterioration of the disease, and treatment must not be delayed.
Storage	**Metered-dose inhalers (MDI):** Store between 20°C and 25°C. Do not puncture or use, or store near heat or open flame. Store with the mouthpiece down. Discard when the counter reads 0. **Dry powder inhalers (DPI):** Store between 15°C and 25°C. Avoid exposure to extreme heat, cold, or humidity. Discard 13 months after opening the foil pouch, or when the counter displays 0, whichever comes first. **Diskus:** Store at ≤30°C. Keep in a dry place. Protect from frost and light. Should be discarded when the counter displays 0. **Injection solution:** Store between 15°C and 30°C. Protect from light. After dilution, discard the unused portion after 24 hours. **Nebulization solution:** Store between 2°C and 25°C. Do not use if the solution changes color or becomes cloudy. Products packaged in foil should be used within 1 week after being removed from the foil. **Oral tablets and syrup:** Store between 20°C and 25°C in a dry place. **N.B.** Refer to the manufacturer's PIL for specific considerations.

Terbutaline

Generic Name	Terbutaline
Dosage Forms/ Strengths	**Syrup:** 1.5 mg/5ml single and in combination, 1.25 mg, 1.5 mg/5ml in combination **Tablets:** 2.5 mg **Solution for nebulizer:** 5mg/2ml
Route of Administration	Oral, inhalation
Pharmacologic Category	Beta2-adrenoreceptor agonists **ATC** Nebulizer solution: R03AC03 Oral dosage forms: R03CC03
Indications	• Relief of severe bronchospasm in bronchial asthma and in chronic bronchitis and other bronchopulmonary disorders in which bronchospasm is present. • Prevention of bronchospasm in bronchial asthma. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Regimen	**Dosing: Adults and the elderly** **Nebulizer solution** One or two ampoules (5 or 10mg) 2-4 times daily. Additional doses may be necessary in acute severe asthma. **Syrup (1.5mg/5ml)** 10-15 ml three times daily. **Tablet** 2.5-5 mg three times daily. Maximum dose 15 mg/day. **Dosing: Pediatrics** **Nebulizer solution** Children (>25 kg): One ampoule (5mg). Children (<25 kg): Not recommended. **Syrup (1.5mg/5ml)** 0.075mg (0.25ml)/kg/ three times daily. Maximum dose 15 ml three times daily. **Tablet** Not recommended for use in children below 12 years (12- 15 years) (~~7 – 15 years~~): 2.5mg/twice to three times daily. Maximum dose: 7.5 mg/day. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Adjustment	**Dosing: Altered kidney function: Adult/Pediatrics** No dosage adjustment necessary. **Dosing: Hepatic impairment: Adults/Pediatrics** Significant hepatic dysfunction: Not recommended because of unpredictable conversion to terbutaline.

Terbutaline

	N.B. Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Contra-indications	• Hypersensitivity to the active substance or to any of the excipients. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Adverse Drug Reactions	**>10%** • **Central nervous system:** Nervousness, restlessness • **Endocrine and metabolic:** Decreased serum potassium, increased serum glucose • **Neuromuscular and skeletal:** Tremor **1% to 10%** • **Cardiovascular:** Hypertension, tachycardia • **Central nervous system:** Dizziness, drowsiness, headache, insomnia • **Dermatologic:** Diaphoresis • **Gastrointestinal:** Dysgeusia, nausea, vomiting, xerostomia • **Neuromuscular and skeletal:** Muscle cramps, weakness **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Monitoring Parameters	• Lactic acidosis and arterial blood gases before increasing the dose • Forced Expiratory Volume 1 **(**FEV1), peak flow, and/or other pulmonary function tests; shortness of breath; BP, heart rate; CNS stimulation; serum glucose, serum potassium; monitor for signs and symptoms of pulmonary edema (when used as a tocolytic: suppress uterine contractions). If used for extravasation management, monitor and document the extravasation site. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Drug Interactions	***Risk X: Avoid combination*** Domperidone, Kratom, Levoketoconazole, Loxapine, Pimozide, Piperaquine, Sertindole, Sotalol, Thioridazine. ***Risk D: Consider therapy modification*** Beta-Blockers (Nonselective), Cocaine (Topical), Linezolid, Methacholine, QT-prolonging Agents (Highest Risk). **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Pregnancy and Lactation	**Pregnancy** • There are no adequate and well-controlled studies in pregnant women. • Use with caution during the first trimester of pregnancy. • Use with caution at the end of pregnancy because of the potential tocolytic effect. **Lactation** • Although terbutaline is released in breast milk, therapeutic dosages are unlikely to have an impact on the newborn. • Transient hypoglycemia has been reported in newborn preterm infants after

Terbutaline

	maternal beta2-agonist treatment. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Administration	**Oral** • It should be taken without regard to food. **Nebulization** • Hold the ampoule upright, twist, and pull off the plastic seal. • The solution in an ampoule must be put into a nebulizer and made into a fine mist before it can be breathed in. It is then inhaled through a face mask or mouthpiece. • If using a face mask, make sure that it is fitted correctly. Be sure to protect your eyes from the mist produced, as it can cause pain or discomfort if it gets into them. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	**Concerns related to adverse effects** • **Cardiovascular effects:** It should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. • **Hypokalemia:** Monitoring of potassium level is required. • **Seizures:** Monitoring CNS stimulation is required, and use with caution in an epileptic patient. As there have been rare reports of seizures in patients receiving terbutaline, seizures did not recur in these patients after the drug was discontinued. • **Immediate hypersensitivity reactions and exacerbation of bronchospasm**: Monitor closely. • **Tocolysis:** Terbutaline has not been approved and should **not** be used for maintenance tocolysis in the outpatient or home setting (beyond 48 to 72 hours). Serious adverse reactions, including death, have been reported. **Disease-related concerns** • **Asthma:** Appropriate use: Do not use as a component of chronic therapy without an anti-inflammatory agent (e.g., inhaled corticosteroids, leukotriene receptor antagonists). • **Deterioration of Asthma:** Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient needs more doses of terbutaline sulfate than usual (e.g., more than twice a week additional "as needed" terbutaline sulfate nebuliser solution), this may be a marker of deterioration of asthma and requires re-evaluation of the patient and the treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment. • **Thyrotoxicosis:** Use with caution. • **Hypertrophic cardiomyopathy:** Should not be used due to the positive inotropic effect of beta2-agonists. • **Severe heart disease:** Use with caution. Should seek medical advice when experiencing chest pain or symptoms of worsening heart disease.

Terbutaline

	• **Diabetes:** Increased serum glucose and aggravation of pre-existing diabetes and ketoacidosis. • **Lactic acidosis**: Sometimes occurs due to overdose. **Dosage forms concerns** • **Sorbitol:** Syrup may contain sorbitol. It is not recommended for patients with rare hereditary problems of fructose intolerance. • **Lactose:** Tablet may contain lactose. It is not recommended for patients with rare hereditary problems, including galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Storage	• **Nebulizer solution:** The ampoule should be opened immediately before use, and any solution remaining after use should be discarded. • Do not store above 25ºC. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Decongestants

Xylometazoline

Generic Name	Xylometazoline
Dosage Form/Strengths	Nasal drops: 0.05%, 0.1% Nasal spray: 1mg/ml, 0.5mg/ml Some products are combined with carbocysteine 5 mg, 10 mg, and dexapanthenol 50 mg/ml.
Route of Administration	Nasal
Pharmacologic Category	Alpha-adrenergic agonist; decongestant; imidazoline derivative **ATC:** R01AA07
Indications	Nasal relief of nasopharyngeal congestion, perennial and allergic rhinitis (including hay fever), and sinusitis. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Regimen	**Dosing: Adults** • Nasal drops 0.1%: 2 – 3 drops in each nostril 3 times daily. • Nasal spray 0.1%: 1 puff in each nostril every 8. Maximum: 3 puffs in each nostril/day. **Dosing: Geriatric** Same as adult dosing. **Dosing: Pediatric** • Children 6 – 11 years old, give 1 – 2 drops of 0.05% formulation in each nostril once or twice daily. Maximum: 2 times in each nostril/day. • Children > 12 years old: 1 puff or drop of 0.1% formulation in each nostril every 8 hours as needed. Maximum: 3 puffs/drops in each nostril per day. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Adjustment	**Renal Impairment** No dose adjustments required. **Hepatic Impairment** No dose adjustments required. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Contra-indications	• Known hypersensitivity to xylometazoline or any of the excipients of the product. • After trans-nasal or trans-buccal surgeries that expose the dura matter e.g., transsphenoidal hypophysectomy. • Rhinitis sicca. • Closed-angle glaucoma. • Inflammation of the skin and/or mucosa of the nasal vestibule. • Patients with phaeochromocytoma or prostatic hypertrophy.

Xylometazoline

	• Coadministration of monoamine oxidase inhibitors (MAOIs) or within 2 weeks after discontinuing MOAIs. • 0.1% formulation is contraindicated in children aged < 12 years. • 0.05% formulation is contraindicated in children < 6 years of age. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Adverse Drug Reactions	**1% to 10%** **Central nervous system**: Headache **Gastrointestinal:** Nausea **Local:** Application site burning **Respiratory:** Dry nose, nasal discomfort **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Monitoring Parameters	No specific monitoring measures are required. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Drug Interactions	***Risk D: Consider therapy modification*** Esketamine, Zavegepant. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Pregnancy and Lactation	**Pregnancy** There are not enough data, so xylometazoline should not be used during pregnancy due to its vasoconstrictive properties. **Lactation** No data available about whether xylometazoline is excreted in breast milk, so it should be used with caution and supervision and after healthcare provider consultation. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Administration	1. Nasal sprays should be primed before first-time use or if the product has not been used for longer than 7 days, by pumping into the air several times until mist is seen coming out. 2. The nose should be cleared before use. 3. The patient should tilt the head slightly to the back and apply the drops or the spray to each nostril. 4. The tip of the dropper or the spray should be cleaned after use. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	• Xylometazoline should be used with caution in patients with the following disorders: - Cardiovascular diseases - Diabetes mellitus - Thyroid disorders - Prostatic hyperplasia or urinary obstruction

Xylometazoline

	- Patients with signs of insomnia, dizziness, and tremor • The use of xylometazoline for prolonged periods causes rebound nasal congestion. • The patient should consult the doctor if symptoms persist longer than 3 days. • It should not be used for > 7 consecutive days in adults, as the prolonged or excessive use may cause rebound congestion and/or atrophy of the nasal mucosa. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Storage	Store below 30 °C, protect from heat. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Human Alpha 1- Proteinase Inhibitor

Omalizumab

Generic Name	Omalizumab
Dosage form/strengths	Powder for injection: 75 mg/0.6 ml, 150mg/1.2 ml.
Route of administration	Subcutaneous injection
Pharmacologic category	Monoclonal Antibody, Anti-Asthmatic **ATC:** R03DX05
Indications	**Asthma** – Treatment of moderate to severe persistent asthma in adults and pediatric patients ≥6 years of age who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. – Limitation: Not indicated for acute bronchospasm or status asthmaticus. **Rhino sinusitis (chronic) with nasal polyps** – Add-on maintenance treatment of chronic rhino sinusitis with nasal polyps in adults (≥18 years) with inadequate response to nasal corticosteroids. **Urticaria (chronic spontaneous)** – Treatment of chronic spontaneous urticaria in adults and adolescents 12 years and older who remain symptomatic despite H1 antihistamine treatment. – Limitation: Not indicated for other allergic conditions or other forms of urticaria.
Dosage Regimen	**Asthma** • 75 to 375 mg SC every 2 or 4 weeks. • Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). **Rhino sinusitis (chronic) with nasal polyps** • 75 to 600 mg SC every 2 or 4 weeks. • Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). • Dosing for allergic asthma and Chronic Rhinosinusitis with Nasal Polyps follows the same dosing principles. The appropriate dose and frequency of omalizumab for these conditions is determined by baseline IgE (IU/mL), measured before the start of treatment, and body weight (kg). The maximum recommended dose is 600 mg of omalizumab every two weeks.

Omalizumab

Table 1: Administration every 4 weeks. Omalizumab doses (milligrams per dose) administered by subcutaneous injection every 4 weeks

	Body Weight (Kg)									
Baseline IgE (IU/ml)	20 - 25*	>25 - 30*	>30 - 40	>40 - 50	>50 - 60	>60 - 70	>70 - 80	>80 - 90	>90 - 125	>125 - 150
30 - 100	75	75	75	150	150	150	150	150	300	300
>100 - 200	150	150	150	300	300	300	300	300	450	600
>200 - 300	150	150	225	300	300	450	450	450	600	
>300 - 400	225	225	300	450	450	450	450	600		
>400 - 500	225	300	450	450	600	600				
>500 - 600	300	300	450	600	600					
>600 - 700	300		450	600						
>700 - 800	Administration every 2 weeks **(Table 2)**									
>800 - 900										
>900 - 1000										
>1000 - 1100										

*Body weights below 30 kg were not studied in the pivotal trials for chronic rhinosinusitis with nasal polyps.

Omalizumab

Table 2: Administration every 2 weeks. Omalizumab doses (milligrams per dose) administered by subcutaneous injection every 2 weeks

Baseline IgE (IU/ml)	Body Weight (kg)									
	20 - 25*	>25 - 30*	>30 - 40	>40 - 50	>50 - 60	>60 - 70	>70 - 80	>80 - 90	>90 - 125	>125 - 150
30 - 100	Administration every 4 weeks (Table 1)									
>100 - 200										
>200 - 300										375
>300 - 400									450	525
>400 - 500							375	375	525	600
>500 - 600						375	450	450	600	
>600 - 700		225			375	450	450	525		
>700 - 800	225	225	300	375	450	450	525	600		
>800 - 900	225	225	300	375	450	525	600			
>900 - 1000	225	300	375	450	525	600				
>1000 - 1100	225	300	375	450	600					
>1100 - 1200	300	300	450	525	600					
>1200 - 1300	300	375	450	525						
>1300 - 1500	300	375	525	600						

Data is not sufficient to recommend doses.

Omalizumab

	*Body weights below 30 kg were not studied in the pivotal trials for chronic rhinosinusitis with nasal polyps.
	
	Urticaria (chronic spontaneous)
	• 150 or 300 mg SC every 4 weeks.
	• Dosing is not dependent on serum IgE (free or total) level or body weight.
	
	Considerations for pediatric patients:
	• In allergic asthma, the safety and efficacy of omalizumab in patients below the age of 6 years have not been established. No data are available.
	• In chronic rhinosinusitis with nasal polyps, the safety and efficacy of omalizumab in patients below the age of 18 years have not been established. No data are available.
	• In chronic spontaneous urticaria, the safety and efficacy of omalizumab in patients below the age of 12 years have not been established. No data are available.
	
	Other considerations related to dosing and treatment duration:
	• Allergic asthma: patients should be assessed 16 weeks after starting treatment. The decision to continue treatment depends on whether the symptoms have improved.
	• Chronic rhino sinusitis with nasal polyps: patients should be assessed after 4 weeks, and the decision to continue treatment should be based on disease severity and symptom control.
	• When starting treatment with omalizumab:
	  ○ If the patient had not received omalizumab within the past year, the dose should be determined based on IgE levels.
	  ○ If treatment with omalizumab was discontinued within the past year, retesting IgE levels cannot be used to guide dose determination, as IgE levels remain elevated for up to 1 year after discontinuation. In such a case, baseline IgE levels should be used.

Dosage adjustment	**Renal Impairment** There are no dosage adjustments; it should be administered with caution. **Hepatic Impairment:** There are no dosage adjustments; it should be administered with caution.
Contra-indications	Severe hypersensitivity reaction to Omalizumab or any component of the formulation.
Adverse Drug Reactions	**>10%** **Local**: Injection-site reaction (asthma: 45%, severe 12%; chronic spontaneous urticaria and chronic rhinosinusitis with nasal polyps: 3% to 5%; may include bleeding at injection site, bruising at injection site, burning sensation at injection site, erythema at injection site, induration at injection site, injection-site pruritus, pain at injection site, residual mass at injection site, swelling at injection site, urticaria at injection site, warm sensation at injection site) **Nervous system**: Headache (children: ≥3%; adolescents and adults: 6% to 12%)

Omalizumab

Monitoring Parameters	Anaphylactic/hypersensitivity reactions (observe patients after the first 3 injections); baseline serum total IgE; monitor for signs of infection.
Drug Interactions	**Risk X: Avoid combination** • Loxapine.
Pregnancy and Lactation	**Pregnancy** • A moderate amount of data on pregnant women (between 300 – 1,000 pregnancy outcomes) based on pregnancy registry and post-marketing spontaneous reports, indicates no malformative or foeto/neonatal toxicity. • Omalizumab crosses the placental barrier. However, animal studies do not indicate either direct or indirect harmful effects with respect to reproductive toxicity • If clinically indicated, omalizumab may be used during pregnancy. **Lactation** • Immunoglobulin G (IgG) is present in human milk, and therefore, it is expected that omalizumab will be present in human milk. Available data in non-human primates have shown excretion of Omalizumab into milk. • The EXPECT study, with 154 infants who had been exposed to omalizumab during pregnancy and through breastfeeding, did not indicate adverse effects on the breastfed infant. • Consequently, if clinically needed, the use of omalizumab may be considered during breastfeeding.
Administration	**Administration** • For subcutaneous injection only. • For patients requiring more than 1 injection to complete a full dose, administer each injection at least 2.5 cm apart from other injection sites. • Administer subcutaneous injection into the front and middle of the thighs or abdomen, avoiding the 5 cm area directly around the navel. The outer area of the upper arms may be used only if a caregiver or healthcare provider is giving the injection. The injection may take up to 15 seconds to administer. • The 300 mg dose may be administered as two subcutaneous injections of 150 mg/mL • The injection site should be exposed to clean skin. • Observe patient for 2 hours after the first 3 injections, and for 30 minutes after subsequent injections. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	• **Anaphylaxis:** Initiate omalizumab therapy in a healthcare setting prepared to manage anaphylaxis, which can be life-threatening, and observe patients for an appropriate period of time after administration. Therefore, medicinal products for the treatment of anaphylactic reactions should always be available for immediate use after omalizumab administration. • **Malignancy:** Malignancies have been observed in clinical studies. • **Acute asthma symptoms:** Do not use for the treatment of acute bronchospasm or status asthmaticus.

Omalizumab

	• **Corticosteroid reduction**: Do not abruptly discontinue corticosteroids upon initiation of omalizumab therapy. • **Eosinophilic conditions**: Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids. • **Fever, arthralgia, and rash**: Stop omalizumab if patients develop signs and symptoms similar to serum sickness. • **Potential medication error related to emergency treatment of anaphylaxis**: Omalizumab should not be used for emergency treatment of allergic reactions, including anaphylaxis. **N.B.** • Omalizumab has not been studied in patients with hyperimmunoglobulin E syndrome or allergic bronchopulmonary aspergillosis or for the prevention of anaphylactic reactions, including those provoked by food allergy, atopic dermatitis, or allergic rhinitis. Omalizumab is not indicated for the treatment of these conditions. • Omalizumab therapy has not been studied in patients with autoimmune diseases, immune complex-mediated conditions, or pre-existing renal or hepatic impairment. Caution should be exercised when administering omalizumab in these patient populations.
Storage	• Following reconstitution, stored for up to 8 hours if refrigerated (2 – 8 °C) or 4 hours if stored at room temperature ≤30 °C. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Inhaled Corticosteroids

Beclomethasone Dipropionate

Generic Name	Beclomethasone Dipropionate
Dosage Form /Strengths	**Oral inhalation aerosol:** 50 micrograms, 100 mcg per actuation **Nasal suspension spray:** • 42 mg/ 100 ml (each puff contains 42 mcg) • 77 mg/ 100 ml **(**each puff contains 77 mcg) **Nasal inhalation aerosol:** 50 micrograms per actuation **Topical cream:** Beclometasone dipropionate 0.25 mg/gm (for non-respiratory use)
Route of Administration	Nasal, oral spray, topical
Pharmacologic Category	Corticosteroid, inhalant (oral), nasal **ATC:** R03BA01, R01AD01, D07AC01
Indications	• **Nasal spray**: Indicated for the treatment and prevention of seasonal and perennial allergic rhinitis, hay fever, and vasomotor rhinitis. • **Oral inhalation**: Offers preventative management of mild, moderate, or severe asthma in adults or children. • **Topical cream:** For the treatment of the various forms of eczema in children and adults, including atopic and discoid eczemas; primary irritant and allergic dermatitis; psoriasis (excluding widespread plaque psoriasis); neurodermatoses, including lichen simplex; intertrigo; discoid lupus erythematosus.
Dosage Regimen	**Nasal spray** • **Adults and children (> 6 years):** 200 to 400 mcg per day (two sprays into each nostril twice daily). Then a single spray into each nostril twice a day if symptoms are controlled. Maximum daily dose 400 mcg. • **Children under 6 years old**: Not recommended **Oral inhalation** Should **not** be used for the treatment of acute asthma attacks in patients. • **Adults (including the elderly):** The usual starting dose is 200 mcg twice daily. In **severe** cases, this may be increased to 600 to 800 mcg daily in 2-4 divided doses

Mild asthma	100-200 mcg/ day in two divided doses
Moderate asthma	200- 400 mcg/ day in two divided doses
Severe asthma	400 - 800 mcg/ day in two divided doses

• **Children**: The usual starting dose is 100 micrograms twice daily. Depending on the severity of asthma, the daily dose may be increased up to 400 micrograms administered in two to four divided doses. **Topical cream** Cream should be applied thinly over the whole of the affected area and gently rubbed in. Initially, the application should be made twice daily, but when

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	improvement is seen, the intervals between applications may be extended, and treatment eventually stopped.
Dosage Adjustment	No dosage adjustment is needed in patients with hepatic or renal impairment
Contra-Indications	Hypersensitivity to the active substance or to any of the excipients
Adverse Drug Reactions	**Frequency is not always defined** **>10%** **Respiratory**: Nasopharyngitis (≤24%; children: 2%, nasal inhalation), epistaxis (2% to 11%, nasal inhalation), pharyngitis (3% to 27%, oral inhalation) **Central nervous system**: Headache (1% to 25%, oral inhalation) **1% to 10%** **Central nervous system**: Dizziness (≤5%), headache (≤5%, nasal inhalation), pain (1% to 5%, oral inhalation), voice disorders (4%, oral inhalation) **Endocrine and metabolic** (nasal inhalation): Adrenal suppression (at high doses or in susceptible individuals), hypercorticoidism (at high doses or in susceptible individuals) **Genitourinary**: Dysmenorrhea (1% to 3%, oral inhalation), viral gastroenteritis (children: 1% to 3%, oral inhalation) **Infection:** Influenza (children: 1% to 3%, oral inhalation) **Gastrointestinal**: Nausea (≤5%, nasal inhalation) (1% to 3%, oral inhalation), oral candidiasis (nasal inhalation, rare; more likely with aqueous solution) (1% to 8%, oral inhalation), vomiting (children: 3%, oral inhalation), diarrhea (children: 1% to 3%, oral inhalation). **Immunologic**: Immunosuppression (nasal inhalation) **Neuromuscular and skeletal**: Decreased linear skeletal growth rate (nasal inhalation), back pain (1% to 4%, oral inhalation), myalgia (children: 1% to 3%, oral inhalation) **Ophthalmic:** Intraocular pressure increased (5%), lacrimation (≤3% nasal inhalation) **Otic**: Otitis (children: 1% to 3%, oral inhalation) **Respiratory**: Sneezing (4%), upper respiratory tract infection (children: 3%, nasal inhalation) (3% to 8%, oral inhalation), nasal congestion (≤3%), rhinorrhea (≤3%), nasal mucosa irritation (erosion) (≤1%), nasal candidiasis (rare; more likely with aqueous solution), pharyngeal candidiasis (rare; more likely with aqueous solution, nasal inhalation), Nasopharyngitis (2% to 9%, oral inhalation), cough (1% to 7%, oral inhalation), viral upper respiratory tract infection (2% to 4%, oral inhalation), oropharyngeal pain (1% to 4%, oral inhalation), sinusitis (3%, oral inhalation), allergic rhinitis (≤3%, oral inhalation) **Miscellaneous**: Fever (children: 3%, oral and nasal inhalation)
Monitoring Parameters	• It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids be regularly monitored. • Use of doses in excess of 1,500 micrograms daily over prolonged periods may lead to adrenal suppression. Monitoring of adrenal reserve may be indicated.

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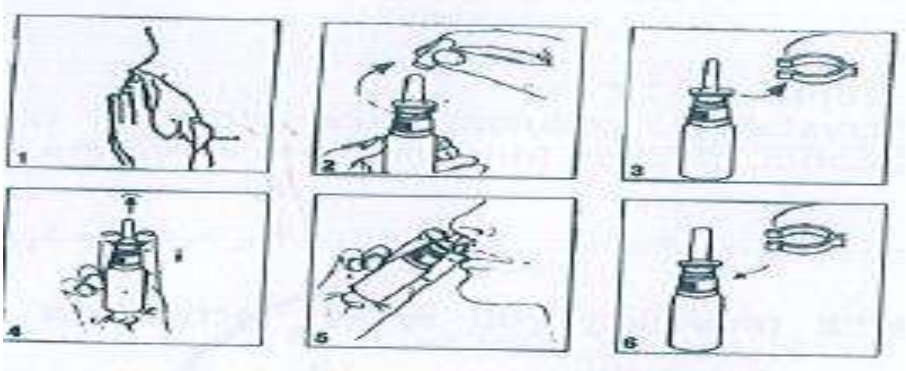
	• Ocular changes, including glaucoma and cataracts. • Signs/symptoms of Candida infection (long-term therapy) • Nasal effects (e.g., epistaxis, nasal discomfort, nasal septal perforation, nasal ulcerations). • FEV1, peak flow, and/or other pulmonary function tests; bone mineral density.
Drug Interactions	***Risk X: Avoid combination (oral inhalation)*** Desmopressin, Loxapine ***Risk D: Consider therapy modification (nasal inhalation)*** Esketamine (Nasal)
Pregnancy and Lactation	**Pregnancy** It should not be used in pregnancy unless the expected benefits to the mother are thought to outweigh any potential risks to the fetus. **Lactation** It should not be used in lactation unless the expected benefits to the mother are thought to outweigh any potential risks to the neonate.
Administration	**Nasal suspension spray** • Clean your nose thoroughly. • Remove the protective cap. • Remove the protective ring locking the pump by pulling it sideways. • Hold the bottle upward. To activate the nebulizing mechanism, depress the metering pump a few times until a visible spray appears. • Insert the nozzle into one nostril while closing the other by pressing it with a finger. Breathe in and, at the same time, press the base of the nasal nozzle. This will deliver one dose of exactly the correct quantity of the active ingredient. Repeat the procedure in the other nostril. • After use, replace the protective ring and the protective cap. • If the mechanism becomes clogged, wash it carefully with warm water, but never insert any pointed objects into the hole.  **Nasal inhalation aerosol** • The dust-cap (if fitted) is removed and the bottle shaken gently. • On first use of the nasal spray, it is prepared for use by pressing down on the white collar using the index finger. The base is supported with the thumb. The

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patient continues to depress the device until the collar stops and then allows it to return to its original position. This action is repeated until a fine spray appears. After which, the spray is ready to use.

- To use the nasal spray, hold the bottle in a slightly sloping position. Open one nostril gently, and carefully insert the applicator into it. Then, close the other nostril.
- The patient slowly begins to breathe in through the nose and, whilst doing so, presses down firmly on the white collar to deliver a fine spray into the nostril. The procedure is completed by breathing out through the mouth.
- Steps 3 and 4 are repeated to deliver a second spray in the same nostril.
- If the pump has not been used for more than a short period of time, re-priming may be necessary (see Step 2 above).

Inhalation aerosol (MDI) oral

- Adults and adolescents 16 years and older: A spacer device should be used only when the total daily dose is 1000 mcg or higher.
- Children and adolescents 15 years and under: A spacer device should be used at all doses, regardless of the prescribed amount.
- During inhalation, the patient should preferably sit or stand. The inhaler has been designed for use in a vertical position.
- If the inhaler is new or has not been used for three days or more, one puff should be released into the air. It is not necessary to shake the inhaler before use because this is a solution aerosol. Instruct the patient to remove the mouthpiece cover and check that it is clean and free from foreign objects.
- The patient should then be instructed to breathe out before placing the inhaler into their mouth. They should then close their lips around the mouthpiece and breathe in steadily and deeply. They must not bite the mouthpiece.
- After starting to breathe in through the mouth, the top of the inhaler should be pressed down. Whilst the patient is still breathing in, the patient should then remove the inhaler from their mouth and hold their breath for about 5 to 10 seconds, or as long as is comfortable, and then breathe out slowly.
- The patient must not breathe out into the inhaler. If another dose is required, the patient should be advised to wait 30 seconds before repeating the procedure just described.
- Finally, patients should breathe out slowly and replace the mouthpiece cover. The patient should be told not to rush the procedure described. The patient must breathe in as slowly as possible before actuation. Inform the patient that if a mist appears on inhalation, the procedure should be repeated.
- It may be helpful to advise children and patients with weak hands to hold the inhaler with two hands, by placing both forefingers on top of the inhaler and both thumbs at the bottom of the device.
- Patients who find it difficult to coordinate actuation with inspiration of breath should be told to use a spacer device to ensure proper administration of the product.

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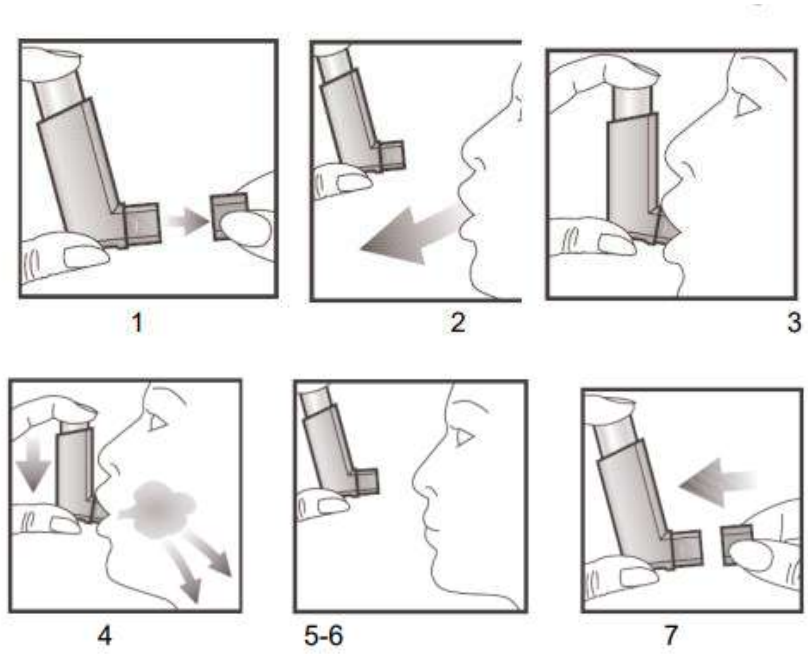
	• Young children may find it difficult to use the inhaler properly and will require help. Using the inhaler with the spacer device with a face mask may help in children under 5 years. • Advise the patient to thoroughly rinse the mouth or gargle with water or brush the teeth immediately after using the inhaler. • The patient should be told of the importance of cleaning the inhaler at least weekly to prevent any blockage. The inhaler must **NOT** be washed or put in water, mouth piece may be cleaned with a dry tissue or cloth.  **Cream for topical use** • Wash your hands • Gently rub the correct amount of cream into the skin until it has all disappeared. • Wash your hands after using the cream. **N.B.** Refer to the manufacturer's PIL for specific considerations.
Warnings/ Precautions	**Nasal spray** • Nasal and paranasal sinus infections should be adequately treated, but are not a contraindication to beclomethasone dipropionate aqueous nasal spray. Medical advice is required in cases of recent nasal injury, surgery, or nasal ulceration. • When switching patients from systemic steroid medication to beclomethasone dipropionate aqueous nasal spray, care should be taken if there is any suspicion that their adrenal function is impaired. • Care must be taken while transferring patients from systemic steroid treatment if adrenal function is impaired. • Beclomethasone dipropionate aqueous nasal spray is generally effective in controlling seasonal allergic rhinitis; however, severe allergy exposure may

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require additional therapy, particularly for ocular symptoms.

- Systemic effects of nasal corticosteroids are uncommon but may occur with prolonged high-dose use, and are less frequent than with oral corticosteroids. Possible effects include adrenal suppression, Cushingoid features, growth retardation in children, ocular effects (cataract, glaucoma), and rare psychological or behavioral disturbances.
- Visual disturbances, such as blurred vision, may occur with systemic or topical corticosteroids. Patients with visual symptoms should be referred to an ophthalmologist to assess for cataract, glaucoma, or rare conditions such as central serous chorioretinopathy.
- Children receiving long-term nasal corticosteroids should have their growth regularly monitored. If growth retardation is observed, treatment should be reviewed and the dose reduced to the lowest effective level, with referral to a pediatric specialist if needed.
- Use of doses higher than recommended may cause clinically significant adrenal suppression; additional systemic corticosteroid cover may be required during stress or surgery.
- Caution is advised in patients with active or latent pulmonary tuberculosis.

Inhalation aerosol (MDI)

- Instruct patients on correct inhaler use to ensure the drug reaches the lungs.
- Take daily as prescribed, even if asymptomatic.
- Not for acute asthma attacks; keep a rapid-acting bronchodilator available.
- Do not stop treatment abruptly.
- Seek medical advice if treatment seems ineffective.
- Increased use of rescue bronchodilators worsens asthma symptoms and needs reassessment of therapy.
- Sudden or progressive deterioration in asthma control may cause a potentially life-threatening condition and needs urgent medical assessment.
- Systemic effects may occur at high/prolonged doses, less likely than oral corticosteroids.
- Possible effects: Cushing’s syndrome, Cushingoid features, adrenal suppression, growth retardation (children/adolescents), decreased bone mineral density, cataract, glaucoma, rare psychological/behavioural effects.
- Dose should be titrated to the lowest effective dose for asthma control.
- Monitor height in children on prolonged therapy; reduce dose if growth slows. Consider referral to a paediatric respiratory specialist if needed.
- Prolonged high-dose inhaled corticosteroids may cause adrenal suppression and risk of acute adrenal crisis, which may be potentiated by trauma, surgery, infection, or rapid dose reduction.
- Symptoms of adrenal crisis: Anorexia, abdominal pain, weight loss, fatigue, headache, nausea, vomiting, hypotension, decreased consciousness, hypoglycaemia, seizures.
- Additional systemic corticosteroid cover should be considered during stress or elective surgery.

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	• Caution when switching from systemic/oral corticosteroids to inhaled therapy; adrenal function may remain impaired for some time. • Patients previously on high-dose or prolonged corticosteroids may be at continued risk; consider specialist advice before elective procedures. • Steroid warning card recommended for patients weaned from oral steroids with impaired adrenal function, to indicate the need for supplementary steroids during stress (illness, surgery, trauma). • Switching from systemic to inhaled therapy may unmask allergies (e.g., allergic rhinitis, eczema); treat symptomatically with antihistamines or topical steroids. • Special care in patients with active or latent pulmonary tuberculosis. • Paradoxical bronchospasm may occur immediately after dosing, with increased wheezing, shortness of breath, or cough. Treat the patient immediately with a fast-acting bronchodilator and discontinue the inhaler. Assess the patient and consider alternative therapy if needed. • Oral hygiene: Rinse mouth after each dose to reduce the risk of Candida infection. • Infections: Special care in patients with viral, bacterial, or fungal infections of the eye, mouth, or respiratory tract. • Visual disturbances: Blurred vision or other visual changes may occur. Refer to an ophthalmologist for evaluation. Possible causes include cataract, glaucoma, or rare conditions such as central serous chorioretinopathy. **Topical use** • Long-term continuous use should be avoided, especially in infants and children, due to the risk of adrenal suppression. • Prolonged use of potent topical corticosteroids may cause facial skin atrophy. • Long-term or inappropriate use of topical steroids may cause rebound flares after stopping. This is more common on delicate skin, such as the face and flexures. • Extra caution is required when treating facial conditions and when applying to the eyelids to prevent eye exposure and possible glaucoma. • Use in children or on the face should be limited to short courses (up to five days) without occlusion. • In psoriasis, topical corticosteroids carry risks such as rebound relapse, tolerance, pustular psoriasis, and toxicity, so careful supervision is essential. • Use appropriate antimicrobials for infected lesions and stop topical corticosteroids if infection spreads, switching to systemic therapy. • Cleanse skin before reapplying dressings, as occlusion promotes infection. • Warn patients of fire risk: avoid smoking or flames, as contaminated clothing, bedding, or dressings ignite easily and remain hazardous even after washing.
Storage	Store below 25°C. Do not refrigerate. Protect from light. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Budesonide: Refer to the Egyptian National Endocrine System Formulary

You can access it through the following link

https://edaegypt.gov.eg/media/wcbezfpv/4-new-code-endocrine-egyptian-national-formulary.pdf

Fluticasone

Generic Name	Fluticasone
Dosage Form /Strengths	**Metered nasal spray:** 27.5 mcg, 28 mcg, 50 mcg /actuation **Topical cream:** 0.05% **Topical ointment:** 0.005% **Monodose nasal drops:** 400 mcg **Suspension for inhalation in a pressurized can:** 125 mcg/dose, 50 mcg **Inhalation powder:** 250 mcg, 100 mcg **Nasal spray solution:** 37.5mg/100 ml
Route of Administration	*Intranasal, intranasal inhalation, oral inhalation, topical*
Pharmacologic Category	Corticosteroids **ATC**: D07AC17, R01AD08, R01AD12 (salt), R03BA05, R03BA09
Indications	**Nasal spray** - Indicated for the prophylaxis and treatment of seasonal allergic and perennial rhinitis symptoms. - Alleviate associated symptoms with allergic rhinitis (pressure and sinus pain) in the age group 4-17. **Oral inhalation** - For maintenance and prophylaxis of asthma in individuals 12 years of age and above **Mono-dose nasal drops** Management of nasal polyps and related nasal obstruction symptoms. **Cream** **Adults** - Alleviation of corticosteroid-responsive inflammatory and pruritic dermatoses manifestations, including - Dermatitis • Atopic dermatitis • Irritant or allergic contact dermatitis • Seborrheic dermatitis • Nummular dermatitis (discoid eczema) - Prurigo nodularis - Psoriasis (excluding widespread plaque psoriasis) - Lichen simplex chronicus (neurodermatitis) and lichen planus - Discoid lupus erythematosus - An adjunct to systemic steroid therapy in generalized erythroderma - Insect bite reactions - Miliaria (prickly heat) **Children and infants over three months** - Recommended for the treatment of atopic dermatitis's inflammatory and itchy symptoms under a specialist's supervision. - Professional advice should be obtained before using it for children with

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	additional corticosteroid-responsive dermatoses. **Ointment** To relieve itchiness and redness associated with certain skin problems **Adults** - Eczema, psoriasis, dermatitis, insect bites, or 'prickly heat'. **Infants and children** - It is used for dermatitis that has not responded to milder steroid creams or ointments, following doctors' advice.
Dosage Regimen	***Adults and Geriatric Dosing*** **Intra-nasal (adults, geriatric, and adolescents 12 years and over)** • Start with the dose of two spray actuations of (27.5 mcg of fluticasone furoate per spray actuation with a total daily dose of 110 mcg) or of (50 mcg fluticasone propionate with a total daily dose 200mcg) in each nostril once daily (total daily dose). **Oral inhalation (adults and children over 16 years)** The starting dose should depend on severity and be titrated down to the lowest dose at which effective control of asthma is maintained. • 100 to 1000 mcg twice daily **Mild asthma:** starting dose is 100 micrograms twice daily. **Moderate and more severe asthma:** starting doses may need to be 250 to 500 micrograms twice daily. **Where additional clinical benefit is expected,** doses of up to 1000 micrograms twice daily may be used. **Mono-dose nasal drops (adults, geriatric, and children over 16 years)** Use half of the 400-mcg container in each nostril once or twice daily. **Cream and ointment** A thin layer is applied on the affected area once or twice daily for four weeks. If there is no improvement, re-evaluate the diagnosis and the treatment. Once improvement is achieved, you should discontinue gradually. ***Children*** **Intra-nasal spray (4-12 years of age)** • Start with the dose of one spray actuation into each nostril once a day, preferably in the morning (27.5 mcg of fluticasone furoate with a maximum daily dose of 55 micrograms) or of (50 mcg of fluticasone propionate with a maximum daily dose of 100 mcg). • In some cases, one spray into each nostril twice daily may be required, so the maximum daily dose is two sprays per nostril. **Oral inhalation for children over 16 years** • Starting dose is 50 to100 microgram twice daily dosing regimen. • The maximum accepted dose in children is 200 mcg twice daily if asthma is not sufficiently controlled. **Cream and ointment (over 3 months)** • Shorter courses than adults and minimum doses that ensure therapeutic effect should be used to avoid local and systemic side effects. • If the condition is not improved within 7-14 days, treatment should be withdrawn, and the child re-evaluated.

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	• Not recommended to use them continuously for more than 4 weeks.
Dosage Adjustment	**Renal impairment** No dosage adjustments are needed. **Hepatic impairment** No dosage adjustments are needed (caution in moderate to severe impairment). Patients with hepatic disease should be closely monitored.
Contra-Indications	• Hypersensitivity to fluticasone or any component of the formulation. • In children <4 years for the intranasal solution. • In children <16 years for oral inhalation and mono-dose nasal drops. • In children less than 3 months for cream and ointment • The use of fluticasone cream is not indicated in the treatment of primary infected skin lesions caused by infection with fungi or bacteria. • Severe hypersensitivity to milk proteins (oral inhalation) • Untreated respiratory tract candidal, bacterial, or HIV infection (intranasal spray) • Do not use oral inhalation as a primary treatment of acute asthma attacks needing intensive care or status asthmaticus. • For cream and ointment: - Pruritus without inflammation - Rosacea - Acne vulgaris - Perioral dermatitis - Perianal and genital pruritus - Untreated cutaneous infections - Primary cutaneous viral infections - Ulceration of the skin - Atrophy of the skin - Fragile skin vessels - Ichthyosis - Juvenile dermatosis - Injuries ulcerated • Dermatoses in infants under three months of age, including dermatitis and nappy rash.
Adverse Drug Reactions	• **Intra-nasal spray** **>10%** **Nervous system**: Headache (4% to 16%) **Respiratory**: Epistaxis (5% to 12%) **1% to 10%** **Endocrine system and metabolic disorder**: Weight gain in adults (1% to 3%). **Gastrointestinal tract**: Abdominal distress in adults (1% to 3%), abdominal pain, diarrhea, and toothache (1% to 3%), nausea and vomiting (3% to 5%). **Local**: Localized erythema in the nasal mucosa and septum in adults (4% to 6%). **Nervous system**: Dizziness, generalized ache or pain (1% to 3%). **Ophthalmic**: Increased intraocular pressure (1% to 3% of adults).

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	Respiratory: Acute sinusitis (5% of adults), blood in nasal mucosa, bronchitis (1% to 3%), cough (4%), dry nose (1% to 3%), flu-like symptoms, nasal congestion (6%), nasal mucosa ulcer including nasal erosions, nasal septal ulceration (3% to 8% of adults), nasopharyngitis (5% to 8% adult), oropharyngeal pain (1% to 3%), pharyngitis (3% to 8%), pulmonary signs and symptoms (7% asthma symptoms), rhinorrhea (1% to 3%), sinusitis (1% to 3%). **Miscellaneous**: Fever (1% to 3%). • **Oral inhalation** **>10%** **Gastrointestinal**: Oral candidiasis (2% to 31%). **Nervous system**: Fatigue and malaise (≤16%), headache (6% to 14%). **Neuromuscular and skeletal**: Arthralgia (17%), myalgia (12%). **Respiratory**: Nasal congestion (16%), rhinitis (3% to 13%), sinusitis (8% to 22%), throat irritation (≤33%), upper respiratory tract infection (6% to 31%). **1% to 10%** **Dermatologic**: Pruritus (6%), skin rash (8%). **Gastrointestinal**: Gastrointestinal distress (≤4%), gastrointestinal pain (≤4%), nausea and vomiting (8% to 9%), toothache (3%), viral gastroenteritis (3%), viral gastrointestinal infection (3% to 5%). **Genitourinary**: Malignant neoplasm of the breast (≤1%). **Infection**: Abscess (≤1%), viral infection (5%). **Nervous system**: Pain (10%), subarachnoid hemorrhage (≤1%), voice disorder (≤9%). **Neuromuscular and skeletal**: Muscle injury (2% to 5%), musculoskeletal pain (3% to 5%). **Respiratory**: Bronchitis (2% to 8%), cough (5% to 9%), hoarseness (≤9%), nasopharyngitis (8%), oropharyngeal candidiasis (3%), oropharyngeal pain (3%), pharyngitis (4%), upper respiratory tract inflammation (2% to 5%), viral respiratory tract infection (5% to 9%). **Miscellaneous**: Fever (7%) • **Topical** **1% to 10%** **Dermatologic:** Burning sensation of skin (≤2%), eczema (<1%); infected skin (1%); herpeticum (<1%), erythema of skin (≤1%), erythematous rash (2%), exacerbation of eczema (2%), pruritus (≤3%; exacerbation: 2%), skin irritation (≤3%), stinging of the skin (≤2%), telangiectasia (2% to 5%), urticaria (≤2%, can be an acute reaction with pharyngeal edema), xeroderma (1%). **Endocrine and metabolic disorder:** HPA-axis suppression (≤4%). **Gastrointestinal:** Diarrhea (1%), vomiting (1%). **Nervous system:** Numbness of fingers (1%).
Monitoring Parameters	- Monitor growth of adolescents and children using stadiometry. - Monitor patients using oral inhalation for Signs/symptoms of Candida albicans infection of the mouth and pharynx (oral candidiasis).

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	- Lung function (forced expiratory volume in 1 second (FEV1) or peak expiratory flow Peak Expiratory Flow (PEF), beta-agonist use, and asthma symptoms should be carefully monitored during withdrawal of oral corticosteroids. - Signs/symptoms of HPA axis suppression/adrenal insufficiency such as fatigue, lassitude, weakness, nausea and vomiting, and hypotension. - Monitor patients with major risk factors for decreased bone mineral density (BMD) with long-term administration of oral inhalation. - Monitor for systemic corticosteroid effects in hepatic impairment. - Possible eosinophilic conditions (including Churg-Strauss syndrome) - Monitor for signs of adverse effects on the nasal mucosa, such as epistaxis, erosion, ulceration, septal perforation, Candida albicans infection, and impaired wound healing, and avoid use in patients with recent nasal ulcerations, nasal surgery, or nasal trauma. - Monitor patients with a change in vision or with a history of increased intraocular pressure (IOP), glaucoma, and/or cataracts.
Drug Interactions	***Risk X: Avoid combination*** Desmopressin (orally inhaled), Loxapine. ***Category D: Consider therapy modification*** CYP3A4 Inhibitors (Strong), Esketamine (Nasal), Fusidic Acid (Systemic), Nirmatrelvir and Ritonavir.
Pregnancy and Lactation	**Pregnancy** - There is insufficient data about the use and safety of fluticasone propionate in pregnant women. However, administration of fluticasone during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. - The dose of inhaled corticosteroid should be titrated to the lowest dose at which effective control is maintained, and treatment with fluticasone should not be stopped abruptly. **Lactation** - There is insufficient data on the use of fluticasone in pregnant women. - Systemic corticosteroids are present in human milk. The use of fluticasone necessitates weighing the medication's benefit against any risks to the infant. - Topical fluticasone should not be applied to the breasts to avoid accidental ingestion by the infant.
Administration	**Administration** **Nasal inhalation** • Should be used by the intranasal route only and avoid eye contact. • Prepare the medication (priming) before using the nasal spray for the first time by pumping 5 times in the air. • Repriming in case of not using it for 30 days or more, or if the nozzle has just been cleaned or lifting the cap for 5 days, by applying pressure on the nozzle multiple times till you see a mist, whilst holding the device upright. • If the bottle has not been used for a week, it should be prepared by

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pumping once.
- Shake before use.
- Clear the nostrils by blowing the nose, insert the nozzle into the nostril, closing the other nostril, and ensuring the nozzle is aimed away from the nasal septum, then spray into the nostril whilst breathing in and then breathe out through the mouth.
- The device should be cleaned with a dry and clean tissue after each use and the cap replaced.
- Once a week, the protection cap and the actuator need to be cleaned with water by immersing them in lukewarm water and leaving them to dry at room temperature. The actuator should not be removed.
- After using the number of labeled doses, discard the bottle.

Nasal drops

- Should be used by the intranasal route only.
- Use one container, and put the remaining back into the foil pack.
- Before use, shake the container to mix well for 30 seconds, then be sure there is no liquid in the neck of the container.
- Twist the top tab to open the container.
- To make sure the drops will reach the right place, you should choose one of these positions:
  - Lean over while you are standing up.
  - Or get on your knees, then bend over.
  - Or tilt your head over the edge of the bed while lying on the bed.
- Clear your nose by blowing, put the top of the container into the nostril.
- Squeeze the container, half the dose in each nostril.
- Keep your head down after putting the drops for one minute.
- Avoid putting the drops on your eyes or damaged skin.

Oral inhalation

- Pull apart the cover of the mouthpiece.
- Check if the inhaler is not working when using it for the first time, by shaking it then pressing the canister away from you into the air.
- Release 2 puffs into the air if you don’t use it for a week.
- Just before using the medication, breathe slowly while standing or sitting upright.
- After removing the cap, check the mouthpiece's cleanliness.
- Shake the container 4 or 5 times before use to mix well and to ensure that any loose objects are removed.
- Breathe out as you can, keep the container upright.
- Between your teeth, put the mouthpiece while closing your lips around it, don't bite.
- Press the canister while breathing in through your mouth steadily and

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	deeply. • Hold your breath for a few seconds after taking out the inhaler. • If your dose is more than one puff, wait for 30 minutes between puffs. • Rinse your mouth, and cover the mouthpiece after use. • You can use both hands if you can't use one hand. **Cream and Ointment** • Use your clean hand to cover the affected area with a thin layer of medication, then massage the medication till it has absorbed. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	• It can take three to four days of treatment (intranasal) to experience the most improvement. • Delayed wound healing: avoid use until healing has taken place in patients had nasal septal ulcers, nasal surgery, or nasal trauma. • Younger children or patients receiving the drug in high doses for prolonged periods may experience hypercortisolism and suppress the hypothalamic-pituitary-adrenal (HPA) axis that may lead to adrenal crisis. Withdrawal of a corticosteroid should be done gradually and cautiously. • Extra caution is required when the patients are shifted from systemic to inhaled corticosteroids to save the patient from possible adrenal insufficiency or withdrawal-associated symptoms. • Concurrent use of ritonavir or any other strong inhibitors of CYP3A4, or adult patients on ≥20 mg prednisone or equivalent/day, may increase fluticasone levels with suppression of HPA. • Hypersensitivity reactions have been reported (including angioedema, rash, hypotension, contact dermatitis, urticaria, bronchospasm, and anaphylaxis) • For severe reactions, the drug should be stopped. • Use of corticosteroids for a long duration may suppress the immune system, which leads to masking symptoms of acute infection, increases the incidence of secondary infection, exacerbate the viral infection severity. • Use with caution and monitor the patient with moderate to severe hepatic impairment. • Patients with respiratory tract (active or latent TB) and other infections should avoid or use with caution. • Local nasal effects: There may be localized Candida albicans infections of the nose and/or pharynx, nasal septal perforation, nasal ulceration, nasal erosion, and epistaxis. Patients should be regularly monitored for any negative nasal effects; if an infection develops, treatment may need to be stopped; if a nasal septal perforation occurs, discontinue the drug. • Ocular disease: Prolonged usage has been linked to open-angle glaucoma and cataracts; use cautiously in individuals with cataracts and/or glaucoma. Regular eye exams should be considered for patients who report changes in their vision or for long-term users. • Pediatrics: Titrate to the lowest effective dose; avoid using greater than recommended dosages as this may result in hypercortisolism, decreased bone mineral density, or suppression of linear growth (i.e., lowering of growth

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	velocity). When young patients receive corticosteroids, even at recommended intranasal levels, there may be a decrease in growth velocity (monitor growth). Use for as little time as possible to relieve symptoms. • To reduce adverse effects, use the lowest effective dose for the shortest amount of time. Systemic corticosteroid withdrawal effects, such as joint/muscle discomfort, lassitude, and depression, have been seen upon stopping inhalation medication. • Before using ketoconazole (for a fungal infection), steroids for asthma, allergies, or skin rash, or medications for HIV infection (such as ritonavir), consult a healthcare professional. • Topical formulas: Use with caution and under supervision in psoriasis to avoid risk of generalized pustular psoriasis, development of tolerance, rebound relapses, and development of local or systemic toxicity. • Not recommended to apply topical formulas on the face for a long period of time, as the face is more prone to atrophic changes. • Use topical formulae with caution when used on the eyelid, to not enter the eyes, as repeated exposure can cause glaucoma and cataract. • Infected inflammatory lesions should be treated. • Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions that have become infected. Withdraw the topical therapy in case of the spread of infection. • Higher incidence of local hypersensitivity reactions and local infection when using topical corticosteroids to treat the dermatitis around chronic leg ulcers. • Ask the doctor if you applied fluticasone to broken skin folds.
Storage	Store below 30°C **Pressurized formulas** • Protect from frost and direct sunlight, do not refrigerate or freeze. • Do not puncture, break, or burn the canister even if apparently empty. • Always keep the cap on. **Nasal drops** • keep them upright in the foil and outer carton. • Do not freeze **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Systemic Corticosteroids

Betamethasone: Refer to the Egyptian National Endocrine System Formulary

Dexamethasone: Refer to the Egyptian National Endocrine System Formulary

Hydrocortisone: Refer to the Egyptian National Endocrine System Formulary

Methyl Prednisolone: Refer to the Egyptian National Endocrine System Formulary

Mometasone: Refer to the Egyptian National Endocrine System Formulary

Prednisolone: Refer to the Egyptian National Endocrine System Formulary

Triamcinolone: Refer to the Egyptian National Endocrine System Formulary

You can access it through the following link

https://edaegypt.gov.eg/media/wcbezfpv/4-new-code-endocrine-egyptian-national-formulary.pdf

Leukotriene Receptor Antagonist

Montelukast

Generic Name	Montelukast
Dosage Form/Strengths	**Oral granules (in sachets):** 4 mg, **Chewable tablets**: 4 mg, 5 mg **Film Coated Tablets**: 5 mg, 10 mg
Route of Administration	*Oral*
Pharmacologic Category	Leukotriene receptor antagonists. **ATC:** R03DC03
Indications	• Prophylaxis and chronic treatment of asthma in patients 12 months of age and older • Acute prevention of exercise-induced bronchoconstriction (EIB) in patients 6 years of age and older. • Relief of symptoms of allergic rhinitis: Reserve use for patients who have an inadequate response or intolerance to alternative therapies, because the benefits of montelukast may not outweigh the risk of neuropsychiatric symptoms in patients with allergic rhinitis. ○ Seasonal allergic rhinitis in patients 2 years of age and older. ○ Perennial allergic rhinitis in patients 6 months of age and older. • **Limitations of Use:** Not indicated to treat an acute asthma attack.
Dosage Regimen	**Dosing by age** • **15 years and older:** one 10 mg tablet. • **6 to 14 years:** one 5 mg chewable tablet. • **2 to 5 years of age:** one 4 mg chewable tablet **or** one packet of 4 mg oral granules daily • **6 months to 23 months:** One packet of 4 mg oral granules daily **Adults and adolescents 15 years of age and older** • **Asthma** 10 mg once daily in the evening. • **Prevention of EIB** One 10 mg tablet at least 2 hours before exercise. • **Seasonal and Perennial Allergic Rhinitis** One 10 mg tablet daily. **Pediatric dosing** • **Asthma** Pediatric patients 6 to 14 years of age: one 5-mg chewable tablet. Pediatric patients 2 to 5 years of age: one 4 mg chewable tablet or one packet of 4 mg oral granules daily. Pediatric patients 12 to 23 months 2 years of age: One packet of 4 mg oral granules daily. ***N.B.: Safety and effectiveness in asthmatic patients less than 12 months of age have not been established.**

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	• **Prevention of EIB** Pediatric patients 6 to 14 years of age: one 5 mg chewable tablet at least 2 hours before exercise. ***N.B.: Safety and effectiveness in patients less than 6 years of age have not been established.** • **Seasonal and Perennial Allergic Rhinitis** Pediatric patients 6 to 14 years of age: one 5 mg chewable tablet daily. Pediatric patients 2 to 5 years of age: one 4 mg chewable tablet or one packet of 4 mg oral granules daily. ***N.B.: Safety and effectiveness in patients less than 2 years of age with seasonal allergic rhinitis and patients less than 6 months of age with perennial allergic rhinitis have not been established.** **N.B.** - Patients with both asthma and allergic rhinitis should take only one dose daily in the evening. - No additional doses of montelukast should be taken within 24 hours of a previous dose. - Patients who miss a dose should take the next dose at their regular schedule without doubling the dose. - All patients should have for rescue a short acting B- agonist. - Daily administration of montelukast for treatment of chronic asthma has not been established to prevent acute episodes of EIB. N.B. Patients should be evaluated after 2 to 4 weeks for response to montelukast treatment. N.B. Discontinue treatment if no clinical response is observed.
Dosage Adjustment	**Renal Impairment** • No dosage adjustment is necessary. **Hepatic Impairment** • Mild to moderate hepatic impairment: No dosage adjustment is necessary. • Severe hepatic impairment: No data.
Contra-indications	Hypersensitivity to the active substance or to any of the excipients.
Adverse Drug Reactions	**1% to 10%** **Dermatologic**: Atopic dermatitis (≥2%), dermatitis (2%), skin infection (≥2%), skin rash (2%), urticaria (≥2%). **Gastrointestinal**: Abdominal pain (≥2%), diarrhea (≥2%), dyspepsia (2%), gastroenteritis (2%), nausea (≥2%), tooth infection (≥2%), toothache (2%). **Genitourinary**: Pyuria (1%). **Hepatic**: Increased serum alanine aminotransferase (≥1%), increased serum aspartate aminotransferase (2%). **Infection**: Influenza (≥2%), varicella zoster infection (≥2%), viral infection (≥2%). **Nervous system**: Dizziness (2%), fatigue (≤2%), headache (≥2%). **Neuromuscular and skeletal**: Asthenia (≤2%). **Ophthalmic**: Conjunctivitis (≥2%), myopia (≥2%).

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	Otic: Otalgia (≥2%), otitis (≥2%), otitis media (≥2%). **Respiratory**: Acute bronchitis (≥2%), cough (3%), epistaxis (≥1%), laryngitis (≥2%), nasal congestion (2%), pharyngitis (≥2%), pneumonia (≥2%), rhinitis (infective; ≥2%), rhinorrhea (≥2%), sinus headache (≥1%), sinusitis (≥1%), upper respiratory tract infection (≥1%). **Miscellaneous**: Fever (2%), trauma (1%). **Neuropsychiatric events** have been reported in all age groups (Adults, adolescents, and pediatrics) taking montelukast. Symptoms include, but are not limited to, agitation, aggressive behavior or hostility, anxiousness, depression, disturbance in attention, disorientation, dream abnormalities, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, and suicidal thoughts and behavior (including suicide), tic, and tremors.
Monitoring Parameters	Neuropsychiatric events, including suicidal thinking/behavior
Drug Interactions	***Risk X: Avoid combination*** Loxapine (inhaled only).
Pregnancy and Lactation	**Pregnancy** Montelukast may be used during pregnancy only if it is considered to be clearly essential. **Lactation** It is unknown whether montelukast/metabolites are excreted in human milk. Montelukast may be used in breastfeeding mothers only if it is considered to be clearly essential.
Administration	**Oral Administration** • **Film-coated tablet** can be taken without regard to meal time and swallowed with a sufficient amount of fluid. • **Chewable tablets** are preferred to be taken 1 hour before or 2 hours after food. • **Oral Granules** - Can be administered regardless of the time of meals. - Can be taken directly in the mouth, or mixed with a one teaspoonful (5 mL) of cold or room temperature breast milk or infant formula, or mixed with a spoonful of cold or room temperature soft food; only rice, carrots, applesauce, or ice cream can be used. - A dose should be given within 15 minutes of opening a sachet (with or without mixing with breast milk, infant formula, or food). If mixed with breast milk, infant formula, or food, montelukast oral granules must not be stored for future use. - Any unused portions should be discarded. - Montelukast oral granules are not intended to be dissolved in liquid other than breast milk or infant formula. But liquids may be taken subsequent to administration. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

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Warnings/ Precautions	**Appropriate use** Montelukast should not be used to treat acute asthma attacks. **Concomitant corticosteroid use** Montelukast should not be abruptly substituted for inhaled or oral corticosteroids. Inhaled corticosteroids should be reduced gradually. **Neuropsychiatric (NP) events** • Montelukast is associated with serious neuropsychiatric events in post-marketing reports. • NP events have been reported in adult, adolescent, and pediatric patients with and without a previous history of psychiatric disorders. • Most NP events have been reported during montelukast administration, but some have been reported after discontinuation. Because the benefits of montelukast may not outweigh the potential risk of neuropsychiatric symptoms in patients with mild cases who can be adequately treated with alternative therapy. Reserve use for patients with allergic rhinitis to those who have an inadequate response or intolerance to alternative therapies. **Eosinophilia** Systemic eosinophilia has been reported in asthma patients treated with montelukast. Patients present with clinical signs of vasculitis (Churg-Strauss Syndrome), a condition that can be treated with systemic corticosteroid treatment. Patients present with clinical signs of vasculitis (Churg-Strauss Syndrome). Even though a causal relationship between montelukast and such events has not been established, patients should be monitored for eosinophilia, vasculitic rash, deterioration of pulmonary symptoms, cardiac complications, and neuropathy. **Risk in Phenylketonuria Patients** Some Montelukast products (4 and 5 mg chewable tablets) might contain substances derived from phenylalanine, e.g., aspartame, which can cause harm to patients with phenylketonuria. **Aspirin Sensitivity** Patients with known aspirin sensitivity should continue to avoid aspirin or NSAIDs while taking montelukast.
Storage	Store below 30 °C in a dry place, and away from light. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Mucolytics and Expectorants

Acetylcysteine

Generic Name	Acetylcysteine
Dosage Form /Strengths	**Granules in sachet for oral solution**: 200 mg, 600 mg **Powder for oral solution**: 600 mg **Effervescent tablet:** 600 mg **Capsule**: 600 mg **Oral syrup**: 100 mg/5 ml **Solution for oral inhalation**: 100 mg/ml **Solution for IV:** 2 gm/10 ml, 5 gm/25 ml, 300 mg/3 ml **Concentrate for solution for IV infusion and inhalation**: 1000 mg /5ml
Route of Administration	*IV, Oral, Inhalation*
Pharmacologic Category	Antidote; mucolytic agent **ATC:** Oral and inhalation: R05CB01**;** Antidote: V03AB23
Indications	**Oral** Mucolytic adjuvant in the therapy of respiratory disorders associated with thick, viscous mucus hypersecretion. **Intravenous** Treatment of paracetamol overdose in patients: a) Who has taken a staggered overdose irrespective of plasma paracetamol level or b) Where there is any doubt over the time of the overdose, irrespective of plasma paracetamol level, or c) Who present with a plasma paracetamol level on or above a line joining points of 100mg/L at 4h and 15mg/L at 15h Staggered is defined as an overdose where the paracetamol was ingested over a period of 1 hour or more.
Dosage Regimen	**Adult dosing** **Mucolytic agent** **Oral**: 600 mg **once** daily or 200 mg three times daily. Based on the evaluation of treatment results, the treating physician may prescribe an increase in dosage. Abundant fluid intake supports the mucolytic effect of acetylcysteine. **Duration of therapy** depends on the nature and severity of the condition and is determined by the doctor. **Inhalation, nebulization (face mask, mouthpiece, tracheostomy)** Acetylcysteine 20% solution (dilute with sodium chloride or sterile water for inhalation): 3 to 5 mL given 3 to 4 times/day or Acetylcysteine 10% solution: 6 to 10 mL of the 10% solution, 3 to 4 times a day

Acetylcysteine

	Treatment of paracetamol overdose The patient should receive a total of 300 mg/kg over 21 hours on 3 consecutive intravenous infusions as follows **First infusion:** Loading dose**:** 150 mg/kg infused in 200 mL over 1 hour. **Second infusion:** 50 mg/kg in 500 mL over the following 4 hours. **Third infusion:** 100 mg/kg in 1 liter over the following 16 hours. **OR** On 2 separate doses infused over a total of 20-hour period as follows: **First infusion:** loading dose**:** 200 mg/kg infused in 1 liter over 4 hours. **Second infusion:** 100 mg/kg in 500 mL over the following 16 hours. **N.B.** If clinically needed, continued treatment with acetylcysteine (at the dose and rate as used in the third infusion) may be necessary. **N.B.** Dosage is calculated using the patient's actual weight with a ceiling weight of 110 kg for obese patients. **N.B.** Doses should be administered sequentially with no break between the doses. **Pediatric** **Mucolytic agent** **Adolescents over the age of 12 years:** Oral: 200 mg three times daily. **Adolescents 14 years and older**: Oral: 600 mg once daily **or** 200 mg three times daily. **Children and adolescents up to 12 years**: Oral: Safety and efficacy are not established. Maximum daily dose: 600 mg/day. **Duration of therapy** depends on the nature and severity of the condition and is determined by the doctor. **Treatment of paracetamol overdose** Dose and regimen are the same as adults; the quantity of IV fluid should be modified considering age and weight to avoid overload. **First infusion:** loading dose: 150 mg/kg over 1 hour given as a 50 mg/mL solution at a rate of 3 mL/kg/h. **Second infusion:** 50 mg/kg over 4 hours given as a 6.25 mg/mL solution at a rate of 2 mL/kg/h. **Third infusion:** 100 mg/kg over 16 hours given as a 6.25 mg/mL solution at a rate of 1 mL/kg/h.
Dosage Adjustment	**Renal impairment** Insufficient data. Renal impairment can reduce clearance, which may result in drug accumulation and increased adverse drug reactions. **Hepatic impairment**

Acetylcysteine

	Insufficient data. Hepatic impairment can reduce clearance, which may result in drug accumulation and increased adverse drug reactions.
Contra-indications	**Mucolytic agent** • Hypersensitivity to acetylcysteine or to any of the excipients. • Children less than 2 years of age. **Treatment of paracetamol overdose** There are no contraindications to the treatment of paracetamol overdose with acetylcysteine.
Adverse Drug Reactions	**Intravenous** **1% to 10%** **Cardiovascular**: Edema (1% to 2%), facial flushing (≤8%), flushing (1% to 3%), tachycardia (3%). **Dermatologic**: Pruritus (3% to 4%), skin rash (4%), urticaria (≤8%). **Gastrointestinal**: Nausea (1%), vomiting (3% to 6%). **Hypersensitivity**: Hypersensitivity reaction (1% to 7%, including severe hypersensitivity reaction). **Respiratory**: Respiratory system disorder (2%; including bronchospasm, cough, dyspnea, respiratory distress, stridor, wheezing), rhonchi (1%), tightness in chest or throat (1%).
Monitoring Parameters	Monitor closely for bronchospasm, particularly in patients with bronchial asthma. **Acetaminophen overdose** - Monitor patient for the development of anaphylaxis or nonimmune anaphylaxis. - monitor serum acetaminophen concentrations, AST, ALT, bilirubin, PT, INR, serum creatinine, BUN, serum glucose, hemoglobin, hematocrit, electrolytes, and fluid balance. - Monitor serum plasma potassium concentration. - The plasma or serum levels of acetaminophen of patients being treated for ingestion of a potentially hepatotoxic quantity of acetaminophen should be obtained at least 4 hours after ingestion and throughout treatment with acetylcysteine. - Assess patient for nausea, vomiting, and skin rash following oral administration. - For the purpose of determining if discontinuation of acetylcysteine is appropriate, the serum acetaminophen concentration, serum transaminases, and PT/INR should be evaluated every 12 to 24 hours. - Pregnancy test when used as an antidote in patients who could become pregnant.
Drug Interactions	There are no known significant interactions.

Acetylcysteine

Pregnancy and Lactation	**Pregnancy** Limited data. Animal studies do not indicate direct or indirect harmful effects. Before use in pregnancy, it may be used as an antidote if the potential benefits outweigh the potential risks **Lactation** Limited data. A risk to the infants cannot be excluded. Potential risks should be balanced against the potential benefits.
Administration	**IV administration** **Preparation** **IV:** Glucose 5% is the preferred diluent; NS 0.9% is an alternative. **Dilutions and rate of infusion**: Refer to dosing. **N.B.** In patients requiring fluid restriction, diluent volume should be calculated to avoid overload. **Oral administration** **Oral:** Mix the contents of one sachet with 150 ml of water until it dissolves completely (within 5 minutes) and administer immediately with or without food. **Capsule or tablet:** should be taken after food with water. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	**Bronchoconstriction** Monitor patients with bronchial asthma. If bronchospasm occurs, acetylcysteine should be discontinued immediately. **Peptic ulcer** • Caution in patients with peptic ulcer or a history of peptic ulcer, especially in concomitant administration with other drugs with known effects of irritation of the gastric mucosa. • If the appearance of gastric discomfort is observed, the clinical situation should be reevaluated. **Duration of use** If after 5 days there is no improvement or other symptoms appear, the clinical situation should be re-evaluated. **Paracetamol overdose indication (IV)** • Acetylcysteine can prevent or reduce the severity of liver damage. It is most effective when administered within 8 to 10 hours of a paracetamol overdose. • Although the efficacy of acetylcysteine diminishes between 10- and 24-hours post-overdose, it should be administered up to 24 hours as it can still be of benefit. It may still be administered after 24 hours in patients at risk of severe liver damage. **Anaphylactoid reactions (IV)**

Acetylcysteine

	• Anaphylactoid hypersensitivity reactions occur with acetylcysteine, particularly with the initial loading dose. • The patient should be carefully observed during this period for signs of an anaphylactoid reaction. • If symptoms develop, temporarily suspend the acetylcysteine infusion, administer appropriate supportive care, and restart at a lower infusion rate. • Once an anaphylactoid reaction is under control, the infusion can normally be restarted at the normal recommended infusion rates. **Fluid overload** • Total volume administered should be reduced for children, patients who weigh less than 40 kg, and those requiring fluid restriction because of the risk of fluid overload, which may result in hyponatremia and seizures, which may be life-threatening. **Coagulation** Changes in hemostatic parameters have been observed in association with acetylcysteine treatment, some leading to decreased prothrombin time, but most leading to a small increase in prothrombin time. **Skin reactions** • Very rarely, serious skin reactions such as Stevens-Johnson syndrome and Lyell syndrome have been reported in temporal association with the use of acetylcysteine. • Patients should be advised to seek immediate medical advice if new skin or mucosal lesions occur and use should be discontinued as a precaution.
Storage	Store at 15°C to 30°C. Sachet: Protect from light, heat, and moisture. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Ambroxol

Generic Name	Ambroxol
Dosage form/strengths	• **Buccal spray solution:** 2.5 mg/spray • **Lozenges:** 20 mg • **Oral drops:** 7.5 mg/ml • **Sustained-release hard gelatin capsules:** 75 mg • **Syrup:** 15 mg/5 ml, 30 mg/5 ml • **Tablets:** 30 mg
Route of administration	***Buccal, Oral***
Pharmacologic category	Local Anesthetic, Mucolytic Agent **ATC:** Mucolytic agent (oral): R05CB06, local anesthetic (buccal): RO2AD05.
Indications	– Buccal: Relief of acute sore throat in adults and children over 12 years old. – Oral: Treatment of acute and chronic disorders of the respiratory tract associated with pathologically thickened mucus and impaired mucus transport.
Dosage Regimen	**Dosing: Children ≥12 years and adolescents, adults, and the elderly** – Immediate release (solution, syrup, tablet): 60 to 120 mg/day in 2 to 3 divided doses. – Extended-release capsules: 75 mg once daily. – Lozenge: 20 mg as needed for up to 3 days (maximum: 6 lozenges/day). – Buccal spray: 10 mg (4 puffs) applied to the throat up to 6 times daily. **Dosing: Children** – 2 to 6 years: 7.5 mg 3 times daily. – 6 to 12 years: 15 mg 2 to 3 times daily. **Dosing: Infants** – 1.2 – 1.6 mg/kg body weight.
Dosage adjustment	**Renal impairment** There is no dosage adjustment needed. Use with caution. **Hepatic impairment** There is no dosage adjustment needed. Use with caution.
Contra-indications	• Hypersensitivity to the active ingredient.
Adverse Drug Reactions	**1% to 10%** **Gastrointestinal:** Dysgeusia, nausea, oral hypoesthesia (including pharyngeal), feeling of numbness in the throat.

Ambroxol

	Frequency not defined **Dermatologic:** Acute generalized exanthematous pustulosis, erythema multiforme, pruritus, Stevens-Johnson syndrome, toxic epidermal necrolysis. **Gastrointestinal:** Abdominal distention, anorexia, bloating, constipation, heartburn, oral paresthesia, stomach discomfort, stomach pain. **Hypersensitivity:** Anaphylactic shock, anaphylaxis, angioedema, itching.
Monitoring Parameters	None.
Drug Interactions	There are no known significant interactions.
Pregnancy and Lactation	**Pregnancy** • Ambroxol crosses the placenta. Avoid use in the first trimester. **Lactation** • Ambroxol is excreted in human milk. • It's recommended to avoid use during lactation.
Administration	• To be taken orally. • May be administered with or without food. • Extended-release capsules: Swallow whole (do not open or chew) with adequate liquid. • Solution drops (7.5 mg/mL): Drops may be dissolved in water. • Buccal spray: Prime the product by puffing into the open air (away from the body): – Before using the product for the first time, prime by puffing 5 times. – After not using the product for a long time, prime by puffing once. Hold the spray bottle upright with the tip pointing to the back of the throat and push the actuator fully down to apply a puff. • If you forget to take ambroxol hydrochloride or take too small a dose, wait until it is time to take your next dose and then continue taking ambroxol hydrochloride as described. **N.B.** Refer to the manufacturer's PIL for product-specific considerations**.**
Warnings/ Precautions	• Use with caution in patients with a history of gastric ulceration because it may disrupt the gastric mucosal barrier. • Buccal preparations are not suitable for the treatment of mouth ulcers. • Use with caution in severe impairment of the kidney or liver. • Anaphylactic reactions have been reported with ambroxol use.

Ambroxol

	• Severe skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis) have been reported with ambroxol. Early symptoms may resemble flu (fever, aches, rhinitis, cough, sore throat) and be mistaken for the illness. Discontinue the treatment. • Use with caution in cough suppressants because it may lead to the development of a dangerous accumulation of secretions owing to the reduction of the cough reflex, and should be undertaken only after careful risk-benefit assessment.
Storage	• Store at room temperature not exceeding 30°C. • Protect from light. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Bromhexine

Generic Name	Bromhexine
Dosage form/strengths	• **Oral drops:** 2 mg/ml. • **Oral solution:** 4 mg/5 ml. • **Oral syrup:** 4 mg/5 ml, 8 mg/5 ml. • **Tablets:** 8 mg.
Route of administration	***Oral***
Pharmacologic category	Mucolytic Agent **ATC:** R05CB02
Indications	– For use as a mucolytic to break down mucus and help clear the chest in conditions accompanied by excessive mucus secretions, such as common cold, influenza, infections of the respiratory tract, or in other conditions where excess mucus is produced.
Dosage Regimen	**Tablets: 8 mg** – Adults and children over 14 years: 1 – 2 tablets three times daily. – Children 6 – 14 years or less than 50 kg: 1 tablet three times daily. **Oral syrup whose concentration is 8 mg/5ml** – Adults and children 12 years and older: 5 mL (8 mg) three times daily when necessary; may be increased to 10 mL (16 mg) three times daily. – Children 6 - 11 years: 5 ml (8 mg) three times a day when necessary. When infection is present, specific antibiotic treatment may be indicated. **Oral syrup whose concentration is 4 mg/5ml** **Adults and children over 12 years** Recommended total daily dose: 10 ml (8 mg) three times daily Recommended maximum daily dose: 15 ml (12 mg) four times daily The recommended maximum daily dose, which may be needed at the commencement of treatment, should not be exceeded. **Children over 5 to ≤ 12 years** Recommended total daily dose: 5 ml (4 mg) four times daily. **Children 2 to ≤ 5 years** Recommended total daily dose: 5 ml (4 mg) twice daily.

Bromhexine

	N.B. Manufacturers may provide different age classifications and dose intervals.
Dosage adjustment	**Renal impairment** There are no dosage adjustments needed. Use with caution in patients with severe renal failure. **Hepatic impairment** There are no dosage adjustments needed. Use with caution in patients with severe liver disease.
Contra-indications	• Hypersensitivity to the active ingredient or excipients.
Adverse Drug Reactions	**Immune system disorders:** Skin and subcutaneous tissue disorders, as well as respiratory, thoracic, and mediastinal disorders. Anaphylaxis and anaphylactic shock (pruritus, rash, urticaria, angioedema, bronchospasm) and others. **Gastrointestinal:** Diarrhea, nausea, vomiting, upper abdominal pain, and other mild gastrointestinal side effects. **Hepatic:** Transient Increase in serum transaminases. **Nervous system:** Dizziness, headache, sweating.
Monitoring Parameters	• None
Drug Interactions	***Risk X: Avoid combination*** None. ***Risk D: Consider therapy modification*** None.
Pregnancy and Lactation	**Pregnancy** – Category A – Bromhexine crosses the placenta. It's recommended to avoid use during pregnancy, especially in the first trimester. **Lactation** – Bromhexine is excreted in human milk. – It's recommended to avoid use during lactation.
Administration	• To be taken orally. • Can be taken with or without food. **N.B.** Refer to the manufacturer's PIL if there are specific considerations.
Warnings/ Precautions	• Tablets are not used in children under 6 years of age.

Bromhexine

	• Use with caution in patients with a history of gastric ulceration because it may disrupt the gastric mucosal barrier. • Care is also advisable in asthmatic patients. • Use with caution in severe impairment of the kidney or liver. • Increased flow of mucus secretions may occur. • Severe skin reactions/ lesions (Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), acute generalized exanthematous pustulosis (AGEP)) have been rarely reported with bromhexine. Early symptoms of Stevens-Johnson syndrome or TEN may resemble influenza (fever, aches, rhinitis, cough, sore throat) and be mistaken for the illness. If new skin or mucosal lesions occur, medical advice should be sought, and bromhexine should be discontinued. • Some dosage forms may contain sorbitol (10.5 g of sorbitol per max. daily dose of 30 mL). Products containing sorbitol may have a laxative effect or cause diarrhea in some people.
Storage	• Store at room temperature not exceeding 30°C, in a dry place. **N.B.** Refer to the manufacturer's PIL if there are specific considerations.

Carbocisteine (Carbocysteine)

Generic Name	Carbocisteine (Carbocysteine)
Dosage Form /Strengths	**Oral syrup** • 100 mg/5 ml, 250 mg/ 5ml alone • (100, 125 mg in combination with guaifenesin 100 mg, oxomemazine 2mg) • 100mg /5 ml in combination with Promethazine HCL 2.5mg) **Capsule:** 375 mg **Tablet:** 375mg (in combination with guaifenesin 225 mg, oxomemazine 5mg) **Granule for oral suspension:** 750 mg **Nasal spray:** 5 mg (in combination with 0.5 mg xylometazoline hydrochloride) 10 mg (in combination with 1 mg xylometazoline hydrochloride)
Route of Administration	*Oral, nasal spray*
Pharmacologic Category	Mucolytic Agent **ATC:** R05CB03
Indications	Mucolytic agent for the adjunctive therapy of respiratory tract disorders characterized by excessive, viscous mucus, including chronic obstructive airways disease. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Regimen	**Adults** **Oral**: 2250 mg in divided doses, to be reduced to 1500 mg daily in divided doses when improvement is obtained, e.g., for normal syrup 15 ml 3 times a day, reducing to 10 ml 3 times a day **Pediatrics: Capsules are not recommended for children** • **2 - 5 years children:** 62.5 mg- 125 mg/ four times daily. • **6 - 12 years children**: 250 mg three times daily. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Adjustment	**Renal impairment** No dose adjustments required. **Hepatic impairment** No dose adjustments required. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Contra-Indications	• Hypersensitivity to the active substance or to any of the excipients. • Use in patients with active peptic ulceration. • Children aged less than 2 years. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**

Carbocisteine (Carbocysteine)

Adverse Drug Reactions	**>10%** **Gastrointestinal:** Diarrhea, nausea, stomach pain **1% to 10%** **Gastrointestinal:** Stomach discomfort **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Monitoring Parameters	No data **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Drug Interactions	***Risk X: Avoid combination*** • Disulfiram, Methotrimeprazine, Metronidazole (Systemic), Secnidazole. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Pregnancy and Lactation	**Pregnancy** No human data. Carbocisteine is not recommended during the first trimester. **Lactation** Whether carbocisteine and/or its metabolites are eliminated in human milk is unknown. It is impossible to rule out a risk to the newborn or infant. It is not advised for nursing mothers to take carbocisteine. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Administration	• **Capsules:** swallow with water. • **Solution/drops:** Do not administer the drops directly into the child's mouth. Use a spoon to collect the drops before administering. **N.B.** Refer to the manufacturer's PIL for specific considerations.
Warnings/ Precautions	***Disease-related concerns*** • **Respiratory disorders**: Use with caution in patients with chronic bronchial asthma or respiratory failure and patients taking antitussive medication. • **Gastroduodenal ulcers**: Use with caution in patients with gastroduodenal ulcers or those taking concomitant medications known to cause gastrointestinal bleeding. If gastrointestinal bleeding occurs, patients should discontinue medication. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Storage	Do not store above 30ºC. Store in the original package. **N.B.** Refer to the manufacturer's PIL for specific considerations.

Guaifenesin

Generic Name	Guaifenesin
Dosage Forms/ Strengths	**Extended-release tablet**: 600 mg, 1200 mg **Tablets:** 100 mg, 200 mg, 225 mg, 400 mg **Capsules:** 100 mg **Oral syrup**: 10 mg/5 ml, 30 mg/5 ml, 50 mg/5 ml, 100 mg/5 ml,100 mg/10 ml, 200 mg/5 ml, 200 mg/15 ml, 33.3mg/5ml **Powder for oral solution:** 200 mg/sachet **Effervescent granules:**100mg/sachet **Rectal suppository:** 66.6 mg/suppository **Guaifenesin is available in different combinations**.
Route of Administration	*Oral, rectal*
Pharmacologic Category	Expectorant **ATC:** R05CA03, R05CA10, R05FA02, R05X
Indications	Symptomatic relief of productive cough in adults and adolescents above 12 years. It helps loosen mucus and thin bronchial secretions and make coughs more productive. **N.B**. Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Regimen	**Adults, the elderly, and children 12 years and over** **Oral immediate release**: 100 - 200 mg, up to 4 times daily. Maximum dose: 1200 mg and not to be more frequently than every 2-4 hours. **Oral modified release (600 mg)**: 1 or 2 extended-release tablets every 12 hours. Do not exceed 4 extended-release tablets in 24 hours (Maximum dose: 2400 mg). If symptoms persist, the patient should consult a doctor. **Oral solution (20 mg/ml):** 10 ml up to 4 times/ day **Children under 12 years of age** Tablets are contraindicated. Oral solution is contraindicated in children under 6 years of age. **Children 6-12 years of age** **Oral solution (20mg/ml):** 5 ml up to 4 times/ day **Suppository:** Above 2 years: 3 suppositories daily. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Adjustment	**Renal Impairment** Not studied. Caution in severe renal impairment. **Hepatic Impairment** Not studied. Caution in severe hepatic impairment. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Contra-Indications	• Hypersensitivity to any of the ingredients • Tablets should not be used in children under the age of 12 years. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**

Guaifenesin

Adverse Drug Reactions	**Frequency not defined** **Central nervous system**: Dizziness, drowsiness, headache. **Dermatologic**: Skin rash. **Endocrine and metabolic**: Hypouricemia. **Gastrointestinal**: Nausea, stomach pain, vomiting. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Monitoring Parameters	No monitoring data needed. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Drug Interactions	***Risk X: Avoid combination*** Disulfiram, Methotrimeprazine, Metronidazole (Systemic), Secnidazole. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Pregnancy and Lactation	**Pregnancy** Limited human data. As a result, guaifenesin is not recommended during pregnancy; avoid preparations contains ethanol. **Lactation** No data. As a result, guaifenesin is not recommended during lactation; avoid preparations contains ethanol. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations.
Administration	**Oral administration** • Do not crush, chew, or break the extended-release tablet • Take with a full glass of water. • Guaifenesin can be administered without regard to meals. **N.B.** Refer to the manufacturer's PIL for specific considerations.
Warnings/ Precautions	**Respiratory disorders** • Patients with the following conditions should not use this product, unless directed by a physician: acute or chronic asthma, chronic cough such as in chronic bronchitis or emphysema, or where cough is accompanied by excessive secretions. • Patient should stop use and ask a healthcare professional if cough persist more than 7days, comes back, or is accompanied by a fever, rash, or persistent headache. These could be signs of serious conditions. • It is not recommended to use cough suppressants with guaifenesin concomitantly. **CNS Effects** • Patients should be advised that they may experience effects such as drowsiness and dizziness during treatment. If these symptoms develop, the patient should avoid potentially hazardous tasks such as driving or operating machinery.

Guaifenesin

	N.B. Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Storage	Store below 30°C. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Xanthines

Aminophylline

Generic Name	Aminophylline
Dosage form/strengths	**Ampoule:** 250 mg /10 ml
Route of administration	I.V.
Pharmacologic category	Phosphodiesterase Enzyme Inhibitor, Nonselective **ATC:** R03DA05
Indications	• Relief of bronchospasm associated with asthma and in chronic obstructive pulmonary disease. • Disease of the cardiovascular system (e.g., an adjunct in the treatment of pulmonary oedema or paroxysmal nocturnal dyspnoea caused by left ventricular heart failure).
Dosage Regimen	***General notes*** • Aminophylline has a narrow therapeutic index; therefore, the dosage should be titrated for each individual and adjusted according to serum level with caution. • Use ideal body weight in dose calculation. • Therapeutic plasma concentrations of theophylline are considered to be in the range of 5 to 20 mcg/ml • Levels > 20 mcg/mL are often associated with toxic effects. • The drug is not recommended for infants under 6 months of age due to the marked variation in theophylline metabolism in infants. **1. Patients not already receiving theophylline products** (a) ***A loading dose (LD):*** 6 mg/kg may be given by slow IV injection at a rate not exceeding 25 mg/min. (b) **The *maintenance dose (MD)*** for the next 12 hours, depending on the status of the patient, may be considered as follows: • Children aged 6 months to 9 years: 1 mg/kg/hour • Children aged 9 years to 16 years and young adult smokers: 0.8 mg/kg/hour • Otherwise, healthy non-smoking adults: 0.5mg/kg/hour • Elderly patients 0.3mg/kg/hour **2. Patients already receiving Theophylline products** • LD (loading dose) should be deferred until serum theophylline levels can be determined or the clinician must carefully select a dose based on the potential benefits and risks. Loading doses are based on the expectation that 0.5 mg/kg (lean body weight) of theophylline will result in a 1 microgram/ml increase in serum theophylline concentration. • Subsequently, MD (maintenance dose) recommendations are the same as those described above.
Dosage adjustment	**Renal Impairment** No dosage adjustment necessary. Use with caution in patients with renal dysfunction **Hepatic Impairment** Use with caution in patients with liver dysfunction.

Aminophylline

Contra-indications	• Hypersensitivity to aminophylline or any component of the product. • Hypersensitivity to the ethylenediamine or those allergic to theophyllines, caffeine, or theobromine. • Administration concomitantly with other xanthine drugs due to the hazard of serious toxicity is increased. • Administration of aminophylline and/or theophylline simultaneously by more than one route or in more than one preparation increases the hazard of serious toxicity. • The use of aminophylline IV in children under 6 months of age is not generally recommended. • Patients with acute porphyria.
Adverse Drug Reactions	**Frequency not defined** **Central nervous system:** Headache, insomnia, irritability, restlessness, seizure, and tremor **Gastrointestinal:** Diarrhea, nausea, vomiting **Genitourinary:** Diuresis (transient)
Monitoring Parameters	• Monitor serum potassium levels during regular therapy. This is essential during combination therapy with beta2-agonists, corticosteroids, or diuretics, or in the presence of hypoxia. • Theophylline levels should be monitored.
Drug Interactions	***Risk X: Avoid combination*** Acebrophylline, Doxofylline, Esketamine (Injection), Pipamperone, Riociguat, Viloxazine. ***Risk D: Consider therapy modification*** Adenosine, Belumosudil, Carbamazepine, Cocaine (Topical), CYP1A2 Inhibitors (Moderate), CYP1A2 Inhibitors (Strong), Diazoxide, Choline (Extended Release), Erythromycin (Systemic), Iohexol, Iomeprol, Iopamidol, Regadenoson.
Pregnancy and Lactation	**Pregnancy** • Theophylline crosses the placenta. • There are no adequate and well-controlled studies in pregnant women. So, it is not known whether theophylline can cause fetal harm or not. • Aminophylline should only be used during pregnancy if considered essential by the physician. • Although the safe use of theophylline during pregnancy has not been established relative to potential risk to the foetus, theophyllines have been used during pregnancy without teratogenicity or other adverse foetal effects. Because of the risk of uncontrolled asthma, their safety during pregnancy when clearly needed is generally not seriously questioned. **Lactation** • Theophylline is present in breast milk. • Theophylline induces irritability or other signs of toxicity in nursing infants and, therefore, should not be used in breastfeeding.
Administration	• **I.V.** as slow intravenous injection or intravenous infusion • Slow IV injection or IV infusion diluted in glucose injection or sodium chloride

Aminophylline

	injection. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	***Disease-related concerns*** • Influenza immunization for those who have active influenza infection or acute febrile illness. Use with caution. • Aminophylline should be given with caution to patients with cardiac failure, chronic obstructive pulmonary disease, renal or hepatic dysfunction, and in chronic alcoholism, since the clearance of aminophylline is decreased. • Aminophylline should be used with caution in patients with peptic ulcer, hyperthyroidism, glaucoma, diabetes mellitus, severe hypoxemia, hypertension, and compromised cardiac or circulatory function, and epilepsy, as these conditions may be exacerbated. • Methylxanthines may increase gastric acidity, and care should be taken when they are used in patients with a history of peptic ulceration. ***Other warnings/precautions*** • To reduce the undesirable stimulating effects of aminophylline on the central nervous and cardiovascular systems, intravenous administration of the drug should be slow and should not exceed a rate of 25 mg/min. • Aminophylline has a narrow therapeutic index, and serum levels should be monitored regularly, particularly during initiation of therapy. • Aminophylline injection should be administered cautiously to patients over 55 years of age. ***Pediatric population*** • Children are particularly susceptible to the effects of theophylline, and care is required when administering aminophylline to children. • There have been reports of seizures in children with theophylline plasma levels within the accepted therapeutic range. • Alternative treatment should be considered in patients with a history of seizure activity. • If aminophylline injection is used in such patients, they should be carefully observed for possible signs of central stimulation.
Storage	• Store at a temperature not exceeding 25° C. • Protect from light. • Do not use if discolored or if crystals are present. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Theophylline

Generic Name	Theophylline
Dosage Form/ Strengths	**Sustained release tablet:** 200 mg, 300 mg And combinations of theophylline anhydrous
Route of Administration	Oral
Pharmacologic Category	Phosphodiesterase enzyme inhibitor, nonselective. **ATC:** R03DA04
Indications	• Treatment and prophylaxis of bronchospasm associated with asthma. • Chronic obstructive pulmonary disease and chronic bronchitis. • Treatment of left ventricular and congestive cardiac failure. **N.B.** Theophylline should not be used as the first drug of choice in the treatment of asthma in children. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Regimen	**Adult and elderly** • Maintenance dose: 200 mg/12 hours. • This may be titrated to either 300 or 400 mg, depending on the therapeutic response. **Pediatric ≥6 years of age** • Maintenance dose: 9 mg/kg/12 hours. • Chronic asthma: 10-16 mg/kg/12 hours. **N.B.** Lower dosages (based on usual adult dose) may be required for adolescents. Theophylline distributes poorly into body fat; therefore, mg/kg doses should be calculated based on lean (ideal) bodyweight. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Dosage Adjustment	**Renal Impairment** No dosage adjustment necessary **Hepatic Impairment** No dosage adjustment necessary **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Contra-indications	• Hypersensitivity to the active substance or to any of the excipients. • Patients with porphyria. • Concomitant administration with ephedrine in children less than 6 years of age (or less than 22 kg). • Theophylline is contraindicated in children under 6 months of age. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**

Theophylline

Adverse Drug Reactions	**Endocrine and metabolic:** Hypercholesterolemia (including increased HDL cholesterol), increased cortisol (urinary free cortisol excretion), increased free fatty acids. **Gastrointestinal:** Nausea, vomiting. **Nervous system:** Headache, insomnia. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Monitoring Parameters	• Plasma theophylline concentrations. • Heart rate, CNS effects (insomnia, irritability); respiratory rate; arterial or capillary blood gases (if applicable). • Monitor response to therapy in patients who are suffering from asthma. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Drug Interactions	***Risk X: Avoid combination*** Acebrophylline, Diazoxide Choline (Extended Release), Doxofylline, Esketamine (Injection), Kratom, Methotrimeprazine, Metronidazole (Systemic), Pipamperone, Riociguat, Secnidazole, Viloxazine. ***Risk D: Consider therapy modification*** Adenosine, Carbamazepine, CYP1A2 Inhibitors (Moderate, Strong), Diazoxide, Choline (Extended Release), Erythromycin (Systemic), Iohexol, Iomeprol, Iopamidol, Methacholine, Regadenoson. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Pregnancy and Lactation	**Pregnancy** – There are no adequate data from well-controlled studies of the use of Theophylline in pregnant women. – Theophylline should not be administered during pregnancy unless clearly necessary. **Lactation** – Theophylline is secreted in breast milk and may be associated with irritability in the infant. Theophylline can be used by breastfeeding women if the expected benefit to the mother is greater than any possible risk to the child. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Administration	• **Tablets** They must be swallowed whole and not broken, crushed, or chewed, as doing so may lead to a rapid release of theophylline with the potential for toxicity. Missed dose – If a patient forgets to take a dose but remembers within 4 hours of the time the dose was due to be taken, the tablets can be taken straight away. The next dose should be taken at the normal time. – Beyond 4 hours, the prescriber may need to consider alternative treatment until the next dose is due.

Theophylline

	N.B. Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	• The patient's response to therapy should be carefully monitored – worsening of asthma symptoms requires medical attention • Use with caution in elderly patients and patients with cardiac disease, hepatic disease, exacerbations of lung disease, hypothyroidism, fever, and viral infections. Due to potential decreased theophylline clearance, dose reduction and monitoring of serum theophylline concentrations may be required. • Use with caution in patients with hyperthyroidism and cystic fibrosis due to potential increased theophylline clearance, so dose increase and monitoring of serum theophylline concentrations may be required. • Use with caution in patients with peptic ulcers because it acts as a gastrointestinal tract irritant and increases gastric secretion. • Use with caution in patients with cardiac disorders because it causes cardiac arrhythmias. • Patients with a history of seizures, caution should be exercised because Theophylline exacerbates the frequency and duration of seizures, and alternative treatment should be considered. • Use with caution in patients with severe hypertension or chronic alcoholism. Caution should be exercised in elderly males with pre-existing partial urinary tract obstruction, such as prostatic enlargement, due to the risk of urinary retention. **N.B.** Refer to the manufacturer's PIL if there are specific considerations for combinations**.**
Storage	Store at a temperature not exceeding 30°C, in a dry place. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Respiratory stimulant

Doxapram

Generic Name	Doxapram
Dosage Form/ Strengths	**Solution for IV Bolus Injection:** 100mg / 5ml ampoules. **Solution for IV Infusion:** 2mg / 1ml, 500ml infusion bag.
Route of Administration	Intravenous
Pharmacologic Category	Respiratory Stimulant **ATC:** R07AB01
Indications	**1. Acute Respiratory Failure (hypercapnia)** Doxapram is indicated to stimulate ventilation in the following cases: • Patients whose blood gases or clinical condition suggest that severe hypercapnia would occur during oxygen therapy. • Patients showing progressive hypercapnia during oxygen therapy. **2. After Anesthesia** • To stimulate ventilation and avoid post-operative pulmonary complications. • To permit the use of effective doses of narcotic analgesics while avoiding respiratory depression. **Note:** Alternate, more preferred treatments have largely replaced the use of Doxapram.
Dosage Regimen	**Use in Adults:** **1. Acute Respiratory Failure (hypercapnia)** • Measure arterial blood gases before administration and every 30 minutes during administration. • Administer Doxapram with oxygen. • The recommended dose is 1 – 4 mg/minute. • The following regimen produces plasma steady states of Doxapram rapidly: 00 – 15 minutes: 4 mg/minute. 15 – 30 minutes: 3 mg/minute. 30 – 60 minutes: 2 mg/minute. 60 minutes onwards: 1.5 mg/minute. Maximum infusion duration is 2 hours 2. **After Anesthesia** **By IV Infusion** • The recommended dose is 2 – 3 mg/minute. • Dosing should be adjusted based on the patient's response. **By Bolus Injections** • 1 – 1.5 mg/kg body weight, given over at least 30 seconds, and repeated every 1 hour if necessary. • Maximum dose is 3 g / day (Lexicomp, 2026; U.S. Food and Drug Administration, 2005). **Use in Pediatrics** Doxapram is not recommended in pediatrics due to a lack of evidence on safety

Doxapram

	and efficacy.
Dosage Adjustment	**Renal Impairment** • The use of Doxapram in patients with altered kidney function has not been studied; therefore, Doxapram should be used with caution in patients with severe impairment. **Hepatic Impairment** • The use of Doxapram in patients with hepatic impairment has not been studied; therefore, Doxapram should be used with caution in patients with severe impairment. • Doxapram is extensively metabolized in the liver.
Contra-indications	• Hypersensitivity to Doxapram or any excipient of the product in use. • Epilepsy and other convulsive disorders. • Cerebral edema. • Cerebrovascular accidents. • Head injuries. • Severe hypertension. • Coronary artery disease. • Hyperthyroidism or thyrotoxicosis. • Proven or suspected pulmonary embolisms. • Status asthmaticus. • Physical obstruction of the respiratory tract, or any condition resulting in the restriction of chest walls, chest muscles, or alveolar expansion. • Solution for bolus injections should not be administered to infants, pregnant or lactating mothers, as it contains benzyl alcohol.
Adverse Drug Reactions	**Frequencies cannot be estimated** **Nervous System:** Pyrexia, Salivation, Hyperactivity, Perineal warmth, Muscle spasticity, increased deep tendon reflexes, Sweating, Headache, Confusion, Muscle fasciculation, Clonus, decreased cerebral blood flow velocity, Flushing, Dizziness, Hallucinations, Convulsions, Bilateral Babinski. **Cardiovascular:** Moderate increase in blood pressure, Bradycardia, Arrhythmias, Extrasystoles, Sinus tachycardia, Chest pain or tightness **Respiratory:** Dyspnea, Laryngospasm, Cough, Bronchospasm. **Gastrointestinal:** Nausea, Vomiting. **Urinary:** Urinary retention, Stimulation of urinary bladder voiding.
Monitoring Parameters	• Arterial blood gases. • Blood pressure. • Heart rate. • Central nervous system status. • Deep tendon reflexes. • Monitor the patient for 30 minutes to 1 hour after recovery from drug-induced CNS depression, as the effect of Doxapram may not outlast the effect of the depressant drug, and CNS depression might recur.

Doxapram

	Overdosage • Overdosing causes hypertension, tachycardia, increased muscle activity, and deep tendon reflexes. • Intravenous diazepam, phenytoin, short-acting barbiturates, and oxygen should be available at the site of administration to manage overdoses.
Drug Interactions	***Risk D: Consider therapy modification*** Inhalational anesthetics: co-administration increases the risk of arrhythmias. The administration of Doxapram should be delayed after the inhalational anesthetic has been eliminated from the body (after 5 half-lives).
Pregnancy and Lactation	**Pregnancy** • The use of Doxapram has been associated in some reports with a delay in the mental development of preterm infants. • Benefits from Doxapram must be weighed against the risks before use. **Lactation:** • It is not known if Doxapram is excreted in human breast milk • The risk to infants cannot be excluded. **Note:** Solution for bolus injections should not be administered to infants, pregnant or lactating mothers, as it contains benzyl alcohol.
Administration	• For intravenous administration only. • Avoid rapid injection and infusion rates. • Administer slowly with careful observation of the patient. • Doxapram products are incompatible with alkaline solutions (unless the manufacturer's instructions specify otherwise) **N.B.** Refer to the manufacturer's PIL if there are specific considerations**.**
Warnings/ Precautions	• Doxapram should be administered concurrently with oxygen to patients with severe irreversible airways obstruction or severely decreased lung compliance, due to the increased work of breathing in these patients. • In patients with bronchoconstriction, Doxapram should be used with β-agonist bronchodilators to reduce their respiratory effort. • Doxapram should be used cautiously in patients with hepatic impairment as it is extensively metabolized by the liver. • Caution is advised when Doxapram is used with sympathomimetics due to the additive pressor effect. • Doxapram should be used with caution in patients treated with monoamine oxidase inhibitors (MAOI). MAOIs can potentiate the effects of Doxapram. • The use of Doxapram should be delayed until volatile anesthetics (e.g., halothane, cyclopropane, enflurane) that sensitize the myocardium to catecholamines have been eliminated. • The respiratory stimulant effect of Doxapram might not outlast the effects of depressant drugs. Therefore, patients should be observed for 30 minutes to 1 hour as CNS depression might recur. • If diluted using glucose solution, the site of administration should be periodically changed to avoid damage to veins.

Doxapram

	• Caution is advised when administering Doxapram to patients with hypermetabolic states, e.g., phaeochromocytoma. • Arterial blood gases and patient response should be monitored during administration. • Doxapram should be discontinued if blood pressure suddenly rises or the patient develops dyspnea. • Doxapram should not be used with mechanical ventilation. • When using Doxapram, it is essential to maintain an adequate airway. It is advised to take precautions against vomiting and aspiration. • The use of Doxapram has been associated in some reports with a delay in the mental development of preterm infants. • Doxapram should be used with caution in patients with hypertension or impaired cardiac reserve. • Some Doxapram products might contain glucose, which should be taken into account when managing patients with diabetes.
Storage	Store at temperatures not exceeding 30 °C. **N.B.** Refer to the manufacturer's PIL if there are specific considerations**.**

Lung Surfactant

Beractant

Generic Name	Beractant
Dosage Form/Strengths	**Sterile suspension for intratracheal administration Vial:** 25 mg/ml (4, 8 ml)
Route of Administration	Intratracheal administration
Pharmacologic Category	Lung Surfactant **ATC:** R07AA02
Indications	It is indicated for prevention and treatment ("rescue") of respiratory distress syndrome (RDS) (hyaline membrane disease) in premature infants.
Dosage Regimen	**Adult, elderly dosing** • Not applicable as it is not used. **Pediatric dosing** • Each dose is 100 mg /kg birth weight (4 mL/kg). • **Prophylaxis:** In premature infants with evidence of surfactant deficiency, give the first dose as soon as possible, preferably within 15 minutes of birth. • **Treatment of infants with RDS confirmed by radiographic and clinical findings:** Give the first dose as soon as possible, preferably by 8 hours of age. • **In prophylaxis and treatment:** Four doses can be administered in the first 48 hours of life. Doses should be administered no more frequently than every 6 hours. • Evidence of ongoing respiratory distress determines whether more dosages are required. Before giving subsequent doses to those who got a preventive dosage, radiographic confirmation of RDS should be obtained.
Dosage Adjustment	**Renal Impairment** No dosage adjustments are provided in the manufacturer's labeling. **Hepatic Impairment** No dosage adjustments are provided in the manufacturer's labeling.
Contra-indications	None
Adverse Drug Reactions	**>10%** **Cardiovascular:** Bradycardia (transient). **1% to 10%** **Respiratory:** Oxygen desaturation.
Monitoring Parameters	• To avoid postdosing hyperoxia and hypocarbia, continuous heart rate and peripheral O2 saturation should be monitored during administration; peripheral O2 saturation, transcutaneous CO2, and confirmatory blood gas analysis should be performed as needed after administration.

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	• After lung compliance improves, monitor respiratory parameters to reduce volutrauma (which is usually interpreted to imply lung overdistension) if the patient is on mechanical ventilation.
Drug Interactions	***Risk X: Avoid combination*** Fexinidazole, Landiolol. ***Risk D: Consider Therapy Modification*** Ceritinib, Fingolimod, Ponesimod, Siponimod.
Pregnancy and Lactation	**Pregnancy** Beractant is only indicated for use in premature neonates. **Lactation** Beractant is only indicated for use in premature neonates.
Administration	• For intratracheal administration only (via the endotracheopulmonary route). • If one person positions and monitors the infant while another provides the medication, the dosing process is made easier. • Make sure the endotracheal tube is properly positioned and patent before administering. The endotracheal tube may be suctioned before administration at the clinician's discretion. Before starting the dosage, the infant should be given time to stabilize. **Preparation** • It should be carefully examined for discoloration before being administered. It ranges from off-white to light brown in color. Reconstitution or sonication is not necessary before using the vial. • To re-disperse, gently swirl the vial (do not shake) if settling happens during storage. • Avoid filtering. Due to the nature of the substance, some surface foaming may occur during handling. • It should be warmed in the hand for at least 8 minutes or by standing at room temperature for at least 20 minutes before administration. Using artificial warming techniques is not recommended. • Preparation should start before the infant's birth if a preventive dose is to be administered. **For endotracheal administration using a 5 French end-hole catheter** • Using a large-gauge needle (e.g., at least 20 gauge), carefully remove all of the contents of the vial into a plastic syringe. • The premeasured 5 French end-hole catheter should be attached to the syringe. Fill the catheter with medication. Discard the excess drug through the catheter, leaving only the total dose to be given in the syringe. • When administering the drug using a 5 French end-hole catheter, administer in four quarter-dose aliquots. Each quarter-dose is administered with the infant in a different position: – Head and body inclined 5-10° down, head turned to the right – Head and body inclined 5-10° down, head turned to the left – Head and body inclined 5-10° up, head turned to the right

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- Head and body inclined 5-10° up, head turned to the left

- First quarter-dose aliquot of the drug:
  - Place the infant in one of the four suggested positions.
  - Insert the 5-French end-hole catheter into the endotracheal tube. The tip of the catheter should protrude just beyond the end of the endotracheal tube above the infant's carina. Instilling it into a mainstem bronchus is not recommended.
  - Over the course of two to three seconds, carefully administer the first quarter-dose aliquot through the catheter.
  - Remove the catheter from the endotracheal tube once the initial aliquot is administered, then manually ventilate the infant for at least 30 seconds or until he is clinically stable. In order to prevent cyanosis, ventilate with enough oxygen and positive pressure to allow for proper air exchange and chest wall excursion.
- Reposition the infant so that the subsequent quarter-dose can be administered once he is stable.
- Use the same methods to administer each remaining quarter-dose.
- Remove the catheter without flushing it after administering the last quarter-dose. Do not make suction unless clinically indicated (e.g., severe airway obstruction)."

Another method for administration

Instillation in Mechanically Ventilated Infants

- Respiratory frequency at 60/minute, inspiration time at 0.5s, and Fi02 at 1.0 are recommended parameters before administration to newborns on mechanical ventilation. At this time, there is no need to alter the inspiratory pressure.
- There are 2 alternative methods of administration for mechanically ventilated infants:
  - The dose is administered by disconnecting the endotracheal tube from the ventilator, inserting a small-diameter catheter, and administering the dose with the infant in a neutral position. The tip of the catheter should lie at the end of the endotracheal tube.

Alternatively

  - The dose can be administered by inserting a small-diameter catheter through a suction port connector without disconnection from the ventilator, with the infant in a neutral position. The tip of the catheter should lie at the end of the endotracheal tube.
- The catheter is fully removed once the dose is given, and if needed, the ventilator is reconnected.

Instillation in Spontaneously Breathing Infants

- **Intubation Surfactant Extubation (INSURE):** In the delivery room or later after admission to the neonatal unit, carefully administer the dose as a single bolus over 1 to 3 minutes while the infant is in a neutral position after intubation and catheter insertion as previously indicated. Use a bagging approach after instillation, and as clinically required, move on to extubation and continuous positive airway pressure (CPAP).

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	• **Less Invasive Surfactant Administration (LISA):** The dose can be given without intubation using a tiny diameter catheter. In such cases, place the catheter directly into the trachea of infants on CPAP with direct visualization of the vocal cords by laryngoscopy and gently inject the dose as a single bolus over 1 to 3 minutes. Remove the catheter as soon as the medication is administered. Throughout the entire process, maintain CPAP treatment and make sure that breathing occurs naturally. **N.B.** Refer to the manufacturer's PIL if there are specific considerations**.**
Warnings/ Precautions	**Adverse effects related issues** **Transient bradycardia:** Bradycardia and low oxygen saturation have been reported during the dosing process. If these happen, discontinue the dosing process and take the necessary steps to improve the condition. Once stabilization has occurred, continue the dosing process. **Nosocomial sepsis:** Treated neonates have a higher risk of nosocomial sepsis after treatment, although this risk was not linked to a higher death rate. **Other warnings/precautions** • **Appropriate use:** It has not been tested for use in newborns weighing less than 600 grams or more than 1,750 grams. • **Lung oxygenation/lung compliance:** Produces quick increases in lung oxygenation and compliance, which may necessitate frequent changes to ventilator settings and oxygen delivery; hyperoxia may happen within minutes after injection. • **Trained personnel:** Impacts lung compliance and oxygenation quickly; limit use to a closely monitored clinical setting with prompt access to medical professionals skilled in ventilator management and intubation of premature neonates.
Storage	• Store unopened vials refrigerated at (2°C to 8°C). Date and time need to be recorded in the box on the front of the carton or vial whenever it is removed from the refrigerator. • Do not shake. Protect from light. • Store vials in carton until ready for use. • Vials are for one-time use and for only one patient. Upon opening, discard the unused drug. • Unopened, unused vials that have been warmed to room temperature (up to 25 °c) may be returned to the refrigerator within 24 hours of warming and stored for future use. • Vial should not be warmed and returned to the refrigerator more than once. • Vial should not be removed from the refrigerator for more than 24 hours. **N.B.** Refer to the manufacturer's PIL if there are specific considerations**.**

Antifibrotics

Pirfenidone

<table>
<tr><td>Generic Name</td><td>Pirfenidone</td></tr>
<tr><td>Dosage Form/Strengths</td><td>Hard Gelatin Capsules: 267 mg</td></tr>
<tr><td>Route of Administration</td><td>Oral</td></tr>
<tr><td>Pharmacologic Category</td><td>Anti-inflammatory Agent; Antifibrotic Agent
ATC: L04AX05</td></tr>
<tr><td>Indications</td><td>Treatment of idiopathic pulmonary fibrosis (IPF) in adults.</td></tr>
<tr><td>Dosage Regimen</td><td><u>Adults and the elderly</u>
• Initiate treatment at a low dose and gradually titrate it to 2403 mg per day over 14 days as follows:
<table><tr><th>Treatment days</th><th>Dosage</th></tr><tr><td>Days 1 through 7</td><td>267 mg three times daily (801 mg/day)</td></tr><tr><td>Days 8 through 14</td><td>534 mg three times daily (1602 mg/day)</td></tr><tr><td>Days 15 onward</td><td>801 mg three times daily (2403 mg/day)</td></tr></table>• The recommended maintenance daily dose of Pirfenidone is 801 mg three times a day with food for a total of 2403 mg/day.
• Dosages above 2403 mg/day are not recommended for any patient.
• Patients should not take 2 doses at the same time to make up for a missed dose.
• Patients should not take more than 3 doses per day.
• If a patient misses 14 days or more, they should restart treatment and gradually increase the dose over 2 weeks to reach the recommended daily amount.
• If treatment is stopped for less than 14 days, patients can continue at their previous daily dose without restarting the gradual increase
<u>Pediatric</u>
Pirfenidone is not used in children for the treatment of idiopathic pulmonary fibrosis (IPF).</td></tr>
<tr><td>Dosage Adjustment</td><td><u>Renal impairment</u>
• No dose adjustment is necessary in patients with mild renal impairment.
• Use with caution in patients with moderate (CrCl 30-50 ml/min) renal impairment.
• It is not recommended for use in patients with severe renal impairment (CrCl <30 ml/min) or end-stage renal disease requiring dialysis
<u>Hepatic impairment</u>
• .No dose adjustment is necessary in patients with mild to moderate hepatic</td></tr>
</table>

Pirfenidone

	impairment. Use with caution. • It is not recommended for use in patients with severe hepatic impairment or end-stage liver disease.
Contra-indications	• Hypersensitivity to the active substance. • A history of angioedema caused by pirfenidone. • Concomitant use of fluvoxamine. • Severe hepatic impairment or end-stage liver disease. • Severe renal impairment (CrCl <30 ml/min) or end-stage renal disease requiring dialysis
Adverse Drug Reactions	**>10%** **Dermatologic:** Skin rash (30%) **Gastrointestinal:** Abdominal pain (24%), decreased appetite (21%), diarrhea (26%), dyspepsia (19%), gastroesophageal reflux disease (11%), nausea (36%), vomiting (13%) **Nervous system:** Dizziness (18%), fatigue (26%), headache (22%) **Respiratory:** Sinusitis (11%), upper respiratory tract infection (27%) **1% to 10%** **Dermatologic:** Pruritus (8%), skin photosensitivity (9%) **Endocrine and metabolic:** Weight loss (10%) **Gastrointestinal:** Dysgeusia (6%) **Hepatic:** Increased serum alanine aminotransferase (≥3 × ULN: ≤4%), increased serum aspartate aminotransferase (≥3 × ULN: ≤4%) **Nervous system:** Asthenia (6%), insomnia (10%), noncardiac chest pain (5%) **Neuromuscular and skeletal:** Arthralgia (10%)
Monitoring Parameters	• Liver function tests (ALT, AST, and bilirubin) should be performed before the initiation of treatment and subsequently at monthly intervals for the first 6 months and then every 3 months thereafter. • Monitor patient's weight. • Monitor serum sodium level.
Drug Interactions	***Risk X: Avoid combination*** Aminolevulinic Acid (Systemic), Givosiran, Porfimer, Stiripentol, Temoporfin, Tobacco (Smoked). ***Risk D: Consider Therapy Modification*** Ciprofloxacin (Systemic), CYP1A2 Inhibitors (Moderate), CYP1A2 Inhibitors (Strong), Diazoxide Choline (Extended Release), Fluvoxamine, and Nerandomilast.
Pregnancy and Lactation	**Pregnancy** • Animal studies show that pirfenidone and/or its metabolites can cross the placenta and may accumulate in amniotic fluid. • High doses (≥1,000 mg/kg/day) in rats caused: o Prolonged gestation o Reduced fetal viability • As a precaution, pirfenidone should be avoided during pregnancy. **Lactation** • It is unknown whether pirfenidone or its metabolites are excreted in human milk.

Pirfenidone

	• Animal studies show that pirfenidone and/or its metabolites are excreted in milk and may accumulate. A risk to the breastfed infant cannot be excluded. • A decision should be made whether to discontinue breastfeeding or pirfenidone therapy, considering the benefits of breastfeeding for the child and therapy for the mother.
Administration	• For oral use • The Capsules are to be swallowed whole with water and taken with food to reduce the possibility of nausea and dizziness. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**
Warnings/ Precautions	• **Hepatic impairment:** Use with caution in patients with mild to moderate hepatic impairment, and it must not be used in patients with severe hepatic impairment. • **Photosensitivity reaction and rash:** Avoid or minimize exposure to direct sunlight (including sunlamps). Patients should be instructed to use a sunblock daily, to wear clothing that protects against sun exposure, and to avoid other medicinal products known to cause photosensitivity. • **Severe skin reactions:** If the patient has developed Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) with the use of Pirfenidone, treatment must be permanently discontinued. • **Dizziness:** Patients should know how they respond to this medicine before doing activities that need alertness or coordination. If dizziness does not improve or if it worsens in severity, dose adjustment or even discontinuation of pirfenidone may be necessary. • **Fatigue:** patients should know how they react to this medicinal product before they engage in activities requiring mental alertness or coordination. • **Weight loss:** Physicians should monitor the patient's weight and, if weight loss is clinically significant, encourage an increase in caloric intake. • **Hyponatremia:** Hyponatremia may occur in patients taking pirfenidone. Symptoms can be mild or not obvious, so regular monitoring of serum sodium is recommended, especially if the patient has nausea, headache, or dizziness.
Storage	Store at a temperature not exceeding 30 ºC, in a dry place. **N.B.** Refer to the manufacturer's PIL for specific considerations**.**

Alphabetical List of Content