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EPVC Mission

Pharmaceutical Vigilance administration is the way through which the processes for authorizing, Regulating , monitoring and evaluating the safety of any pharmaceutical product or medical device take place, in addition to disseminating any safety information for public health programs, healthcare professionals, and the Egyptian citizen.

The Pharmaceutical vigilance administration is an integral part of the Central Administration of Pharmaceutical Care that works on the enhancement of the pharmaceutical services to guarantee safe and effective use of medications in Egypt, under the patronage of the Egyptian Drug Authority.

Newsletter

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Safety Information : Levamisole Human Market Withdrawal and Veterinary Considerations

Introduction

A safety update regarding medicinal products containing the active pharmaceutical ingredient Levamisole. Originally authorized as an anthelmintic agent to treat parasitic worm infections, recent international assessments have identified severe, unpredictable risks to the central nervous system associated with its use. Following continuous pharmacovigilance monitoring and regulatory determinations made by global reference authorities—most notably the European Medicines Agency (EMA)he Egyptian Drug Authority (EDA) has evaluated the risk-benefit balance of Levamisole and issued regulatory mandates concerning its registration and market availability in Egypt.

Background

Levamisole acts primarily by stimulating nicotinic acetylcholine receptors, which are proteins found on the surface of the worm's nerve cells. This leads to rapid paralysis of the worm's muscles, preventing movement and allowing it to be expelled from the gut of the infected person. However, long-term and short-term administration has been linked to significant safety concerns across international regulatories:

Safety Concerns & Global Regulatory Actions:

European Medicine Agency (EMA/PRAC): On February 13, 2026, the Pharmacovigilance Risk Assessment Committee (PRAC) recommended the withdrawal of marketing authorizations for Levamisole-containing medicines across the European Union. The PRAC review concluded that levamisole can rarely cause serious, debilitating, and potentially life-threatening leukoencephalopathy (damage to the brain's white matter), particularly if left untreated. This condition may occur after a single dose, with symptoms developing up to several months after treatment. As no effective risk-reduction measures or identifiable high-risk groups were established, and alternative treatments for mild parasitic worm infections are available, PRAC concluded that the benefits of levamisole no longer outweigh its risks and recommended withdrawal of its marketing authorizations in the European union

Other Authorities (e.g. Switzerland): Product warnings highlight veterinary restrictions (such as withdrawal periods due to excretion in cattle milk) .

What Has Been Done

Following safety reviews conducted by the General Administration for Pharmaceutical Vigilance/Emerging Safety Issues, formal evaluations were referred to technical and specialized regulatory committees within the Egyptian Drug Authority:

Pharmacovigilance Committee Review & Major Key Achievement (February 26, 2026):

Evaluated the EMA/PRAC decision dated February 13, 2026, alongside historical decisions from the US FDA and other reference authorities, and recommended aligning with the EMA decision to withdraw Levamisole products from human medicinal use.

Key PV Achievement : Through comprehensive research and signal detection beyond routine human safety evaluations, the PV team successfully uncovered critical safety evidence from Swissmedic regarding the excretion of Levamisole in cow milk. Recognizing the potential public health risk of residue exposure through dairy consumption, the PV Committee proactively expanded the scope of safety intervention and recommended referring veterinary formulations to the Veterinary Products Registration Committee. This proactive initiation ensures holistic consumer protection across both human health and animal product safety channels.

Noted that there were earlier PV committee recommendations in Sep 2023 to withhold/suspend human product registration.

Specialized Scientific & Evaluation Committees:

The Scientific Assessment Committee for Hepatology and Gastroenterology endorsed safety measures against maintaining human registrations.

Technical Committee for Drug Control Decisions:

Formally rejected receiving new human registration applications and cancelled all pending human registrations under evaluation containing Levamisole.

The General Administration of Veterinary Products reported that, regarding the Pharmacovigilance Committee's decision concerning the active substance Levamisole, the Specialized Scientific Committee for Veterinary Medicines and Feed Additives emphasized the importance of using the active substance (Levamisole) in veterinary medicine for treating parasitic worm infections, given its economic and therapeutic value as an effective and safe treatment to preserve livestock. Furthermore, the Committee affirmed the prohibition of using this active substance in dairy animals producing milk for human consumption.

References

1. ***EMA :*** *Click here*
2. ***Swissmedic :*** *Click here*
3. ***EDA:*** *Click here*

Local Case Safety Report: Serious Case Following an Extemporaneous "Weight-Gain" Mixture

This case highlights the serious medication-safety risks associated with using adverse drug effects as intended therapeutic outcomes, particularly when multiple medicines are combined for an unapproved purpose in an adolescent without appropriate medical supervision.

Case at a Glance

A 13-year-old female patient diagnosed with diabetes mellitus, hypertension, ovarian cysts, and amenorrhea following the use of an extemporaneously prepared mixture dispensed by a community pharmacy for weight gain.

The mixture was reported to contain a product contains (Chlorpheniramine maleate, Dexamethasone), one blister strip of a product contains (Bromelains, Foeniculum vulgare, Matricaria chamomilla, Mentha x piperita, Pimpinella anisum, Zingiber officinale rhizome), and one blister strip of a product contains (Cyproheptadine hydrochloride).

However, the exact quantities, administered doses, dosing frequency, and duration of treatment were not confirmed.

Following use of the mixture, the patient reportedly experienced no weight gain and developed amenorrhea lasting three months. Subsequent investigations revealed markedly elevated blood glucose and HbA1c levels. The patient was referred to an endocrinologist for further assessment, which reportedly confirmed hypertension and diabetes mellitus. The diabetes mellitus was reported to be attributed to dexamethasone exposure.

The reported reactions were severe, and the case was considered serious. The suspected mixture was discontinued; however, the reported reactions persisted, indicating a negative dechallenge. At the time of reporting, the patient had not recovered.

Background:

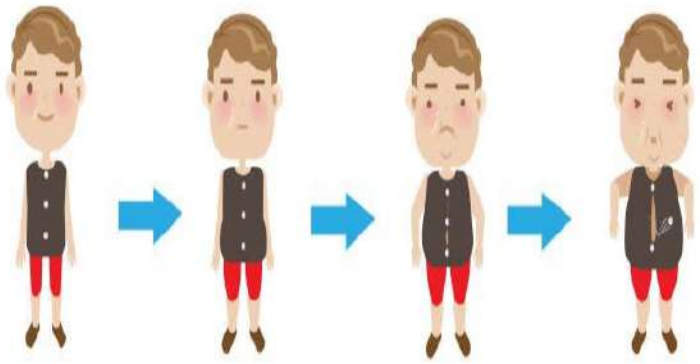
Pharmacological Actions

1st Product

Contains dexamethasone, a systemic corticosteroid with potent glucocorticoid and anti-inflammatory activity, and chlorpheniramine hydrochloride, a first-generation H1-antihistamine.

Dexamethasone exerts profound metabolic effects and modifies immune and inflammatory responses. Systemic corticosteroid exposure is associated with several endocrine and metabolic effects, including decreased carbohydrate and glucose tolerance, hyperglycemia, manifestation of latent diabetes mellitus, menstrual irregularities, increased appetite, and weight gain. Dexamethasone and other corticosteroids are also associated with hypertension and, in pediatric patients, suppression of growth.

Chlorpheniramine competitively antagonizes histamine at H1 receptors and may produce CNS effects, particularly sedation and drowsiness.



2nd Product:

Contains cyproheptadine hydrochloride, a first-generation antihistamine with anti-serotonergic, anticholinergic, and sedative properties. Cyproheptadine hydrochloride is associated with increased appetite and weight gain; however, these are recognized effects of the drug and should not be confused with an indication for unsupervised weight-gain therapy.

Cyproheptadine hydrochloride may also produce CNS depression. Antihistamines can have additive effects when administered with other CNS depressants.

3rd product

The Product is a herbal and digestive-enzyme dietary supplement contains (Bromelains, Foeniculum vulgare, Matricaria chamomilla, Mentha x piperita, Pimpinella anisum, Zingiber officinale rhizome), used to relieve digestive complaints such as indigestion, bloating, gas, and abdominal discomfort, particularly following heavy meals.

Its apparent inclusion in this mixture may have been intended to facilitate digestion and food intake as part of the attempted weight-gain regimen. However, improvement of digestion or appetite should not be interpreted as an established indication for pharmacological weight-gain therapy.

Indications

Dexamethasone: is intended for allergic and inflammatory conditions in which antihistamine and corticosteroid therapy is clinically appropriate. Weight gain is not an approved therapeutic indication.

Cyproheptadine Hydrochloride: is indicated for allergic conditions including perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis, urticaria and angioedema, and other specified allergic reactions.

Bromelains, Foeniculum vulgare, Matricaria chamomilla, Mentha x piperita, Pimpinella anisum, Zingiber officinale rhizome: is used as a digestive supplement to help relieve symptoms of indigestion and gastrointestinal discomfort.

Medication-Safety Risks Identified in This Case

1. Inappropriate Use of Medicines for Weight Gain

The major medication-safety concern in this case is the use of a combination of medicines for a purpose that was not supported by their established therapeutic indications.

The mixture appears to have exploited adverse or secondary pharmacological effects—particularly increased appetite and weight gain—as the intended therapeutic objective.

Weight gain is a recognized adverse effect of systemic corticosteroids such as dexamethasone, while cyproheptadine hydrochloride may cause increased appetite and weight gain. However, the occurrence of an adverse effect does not by itself justify using a medicine to deliberately produce that effect, particularly when the patient is exposed simultaneously to the medicine's other potentially serious adverse effects. In this case, the intended outcome of weight gain was reportedly not achieved, while the patient developed multiple serious medical problems.

2. Inappropriate Corticosteroid Exposure and Failure to Consider the Full Risk Profile

The use of dexamethasone for weight gain represents a particularly important safety concern.

Systemic corticosteroids may cause substantial endocrine and metabolic disturbances. Reported adverse effects of dexamethasone and other corticosteroids include decreased glucose tolerance, hyperglycemia, manifestation of latent diabetes mellitus, menstrual irregularities, hypertension, increased appetite, weight gain, Cushingoid changes, gastrointestinal complications, infection-related risks, and suppression of growth in pediatric patients.

The patient reportedly developed markedly elevated blood glucose and HbA1c levels and was subsequently diagnosed with diabetes mellitus. Although the available information does not establish definite causality, corticosteroid exposure represents a biologically plausible contributor to the reported disturbance in glucose metabolism.

Similarly, amenorrhea itself may not be specifically listed

as an adverse reaction; however, menstrual irregularities are recognized with systemic dexamethasone/corticosteroid exposure. [Therefore, the patient's three-month amenorrhea may be clinically compatible with this broader recognized endocrine effect, although alternative causes cannot be excluded.

The reported hypertension is also clinically relevant because hypertension is among the recognized adverse reactions associated with systemic corticosteroid therapy.

3. Increased Vulnerability Due to the Patient's Age

The patient was only 13 years old. Systemic corticosteroid exposure in pediatric patients requires particular caution. Pediatric patients receiving corticosteroids should be monitored for parameters including blood pressure, weight and height, and systemic corticosteroid treatment may reduce growth velocity even at relatively low systemic doses. The use of a corticosteroid-containing mixture for a non-established weight-gain purpose therefore exposed an adolescent patient to avoidable endocrine, metabolic, cardiovascular, and developmental risks without a clearly established therapeutic benefit.

4. Inappropriate combination and Additive Safety Risks:

Combining several products to exploit their appetite- or weight-related effects increases medication exposure without necessarily providing an evidence-based therapeutic benefit.

The combination also creates the potential for overlapping adverse effects.

Both chlorpheniramine maleate and cyproheptadine hydrochloride are first-generation antihistamines with sedating properties. Cyproheptadine labeling warns that antihistamines may have additive effects with other CNS depressants. The supplied interaction reference similarly identifies the potential for additive CNS depression and recommends monitoring for manifestations such as sedation and somnolence.

Although CNS depression was not reported in this patient, the potential additive CNS-depressant effect remains an important medication-safety concern. Continued or excessive

exposure could potentially result in clinically significant CNS effects. In pediatric patients, antihistamine overdosage has been associated with serious CNS manifestations, including CNS depression, convulsions, and, in severe cases, respiratory or cardiac arrest.

5. Use Without Adequate Medical Assessment, Supervision, or Monitoring

The mixture was reportedly obtained from a community pharmacy specifically for weight gain, while the available case information does not document a medically established indication for any of its components for this purpose.

Before exposing an adolescent to medicines capable of affecting glucose metabolism, blood pressure, endocrine function, growth, and CNS activity, an appropriate clinical assessment and benefit–risk evaluation are essential.

The case also demonstrates the importance of knowing the exact active ingredients, strengths, doses, treatment duration, and potential interactions of every component of an extemporaneously prepared mixture.

In this report, several of these critical exposure details could not be confirmed, further complicating assessment and management of the resulting adverse events.

Recommendations for Healthcare Professionals

1. Do Not Use Adverse Drug Effects as Therapeutic Strategies

Healthcare professionals should not intentionally use undesirable effects such as corticosteroid-associated weight gain as a substitute for an evidence-based approach to managing underweight or appetite concerns.

2. Avoid Unjustified Corticosteroid Exposure

Systemic corticosteroids should only be used when a clinically appropriate indication exists and after considering the individual patient's benefit–risk profile. Their use solely to promote weight gain should be avoided.

3. Exercise Particular Caution in Children and Adolescents

Before initiating medicines with endocrine, metabolic, cardiovascular, or growth-related effects in pediatric patients, healthcare professionals should carefully assess the indication, dose, duration, potential alternatives, and monitoring requirements.

4. Assess the Entire Combination, Not Only the Intended Effect

When multiple medicines are used together, healthcare professionals should evaluate the complete safety profile of each component and identify overlapping or additive risks, including sedation, CNS depression, metabolic abnormalities, and other clinically significant adverse effects.

5. Ensure Appropriate Monitoring

When systemic corticosteroid therapy is clinically necessary, appropriate monitoring should be considered according to the patient's age, clinical condition, dose, and duration of exposure. Relevant parameters may include blood glucose, blood pressure, weight, height/growth, and signs of other corticosteroid-related complications.

6. Counsel Patients and Caregivers Against Unsupervised Weight-Gain Mixtures

Patients and caregivers should be advised that medicines or pharmacy-prepared mixtures promoted for rapid weight gain may contain pharmacologically active substances capable of causing serious harm. An increase in appetite or body weight does not indicate that a product is safe or appropriate for this purpose.

7. Report Suspected Adverse Drug Reactions and Medication-Safety Concerns

Suspected adverse reactions associated with compounded or extemporaneously prepared mixtures should be reported to the appropriate pharmacovigilance system, particularly when the exact composition, dose, or duration of exposure is uncertain.

Pharmacovigilance Take-Home Message

An adverse effect is not a therapeutic indication.

Using medicines because they can cause increased appetite or weight gain may expose patients to the complete spectrum of their pharmacological risks. This concern is particularly important in children and adolescents and with systemic corticosteroids.

Know the indication. Assess every ingredient. Consider the patient's age. Evaluate additive risks. Monitor appropriately. Counsel patients and caregivers. Report suspected medication-related harm.

References

1. ***Dexamethasone :*** *Click here*
2. ***Chlorpheniramine: :****Click here)*
3. ***Cyproheptadine :*** *Click here*

Safer Medicines, Safer Care: Pharmacovigilance Awareness in Practice

Safer Medicines, Safer Care: Pharmacovigilance Awareness in Practice
As part of the ongoing efforts to strengthen pharmacovigilance awareness among healthcare professionals, an awareness and training session was conducted in September 2026 at Saudi German Hospital Cairo.



The session introduced the fundamentals of pharmacovigilance, highlighting the role of healthcare professionals in identifying, documenting, and reporting suspected adverse drug reactions (ADRs). Particular emphasis was placed on the importance of timely and complete reporting in supporting medication safety and the detection of potential safety signals.
The training also focused on drug-related problems, with special emphasis on medication errors, including their potential impact on patient safety and the importance of recognizing, reporting, and preventing such events.
Through practical discussion and examples, participants were encouraged to strengthen their role in promoting a culture of safety, improving reporting practices, and contributing to the prevention of medication-related harm.

Participation in Gastro Egypt Annual Medical Conference

The Pharmaceutical Vigilance General Administration participated in the Gastro Egypt Annual Medical Conference by delivering a lecture entitled “The Role of Pharmacovigilance in Biological Therapy Monitoring” as part of the Clinical Pharmacy Workshop. The lecture highlighted the importance of pharmacovigilance in promoting the safe and effective use of biological therapies, with emphasis on the identification, assessment, monitoring, and reporting of adverse drug reactions and other safety concerns associated with biological medicines.



Gastro Egypt is an annual medical conference organized under the auspices of the Egyptian Society of Gastroenterology and Inflammatory Bowel Disease (ESGID). The conference brings together leading gastroenterologists, hepatologists, endoscopy specialists, and other healthcare professionals to discuss recent clinical updates, research findings, and advances in gastrointestinal and hepatobiliary care.

Egyptian Drug Authority Participates in the 44th Annual Meeting of the WHO Program for International Drug Monitoring



The Egyptian Drug Authority (EDA), represented by Dr. Reem Tarek El Sayed, Head of the ICSR Unit, Pharmacovigilance Department, participated in the 44th Annual Meeting of the World Health Organization Program for International Drug Monitoring (WHO PIDM), held in San José, Costa Rica, in September 2026. The meeting brought together representatives from national pharmacovigilance centers and regulatory authorities worldwide to exchange experiences, discuss emerging challenges, and explore opportunities to strengthen global medicine safety monitoring.

EDA's participation reflects Egypt's continued engagement in international efforts to advance pharmacovigilance and strengthen collaboration among member countries. Discussions addressed the evolving role of digital technologies, the importance of timely safety data exchange, and the development of more efficient and integrated approaches to detecting, assessing, and





preventing adverse drug reactions.

The meeting also provided an opportunity to share national experiences and contribute to discussions on strengthening cooperation between national regulatory authorities and national immunization programs, supporting a more comprehensive approach to monitoring the safety of medicines and vaccines.

EPVC Tips On Pharmacovigilance

Think Safety at Every Step

Off-label use means using a medicine outside its approved product information, such as for a different indication, dose, route of administration, or patient population.

Assess: Evaluate the potential benefits and risks based on scientific evidence and clinical judgment.
Inform: Explain the reason for off-label use, expected benefits, and potential risks to the patient, as appropriate.
Monitor: Follow the patient's response and watch for suspected adverse reactions or lack of efficacy.
Report: Report suspected adverse reactions associated with off-label use through the appropriate pharmacovigilance reporting system.
Remember: Off-label use does not mean inappropriate use, but careful assessment, monitoring, and safety reporting remain essential.

Your medicine should help you—not harm you.

You can report any ADR on:
Email: pv.followup@edaegypt.gov.eg
Hotline: 15301
Website: (click Here)
Or report through your pharmacy / product distributor / company hotline — they are required to forward it to EDA.

Visit EDA website to find all medicine- related news, updates and alerts *Click here*

You will find all EPVC Newsletters and DHPCs here

You will also find all alerts regarding counterfeited and falsified products released by Central Administration of Operations *here*

One report counts

A call for reporting

Please remember that you can report safety information of medicines to EPVC using the following communication information:

What is Pharmacovigilance

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug- related problem.

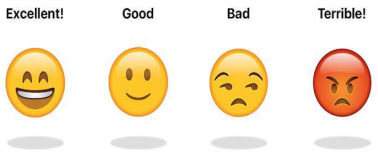
What is the Egyptian Pharmaceutical Vigilance Center?

With the increasing demand for patient's safety which is becoming more stringent, . The Egyptian Pharmaceutical Vigilance Center was established to be responsible for the safety monitoring of the pharmaceutical products throughout its lifecycle and it is the regulatory authority regarding Pharmacovigilance and its applications .

EPVC monitors the safety of all types of pharmaceutical products, including human medicines, biological products, supplements, cosmetics, veterinary medicines, medical devices, Biocides and pesticides

Participate with us

We invite you to take a quick survey on how much our communication with you is effective
We value your feedback! Help us enhance our communication by taking a quick survey. Your insights are crucial in ensuring we meet your expectations.
Survey Link: (Click Here)



Thank you for your valuable input

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