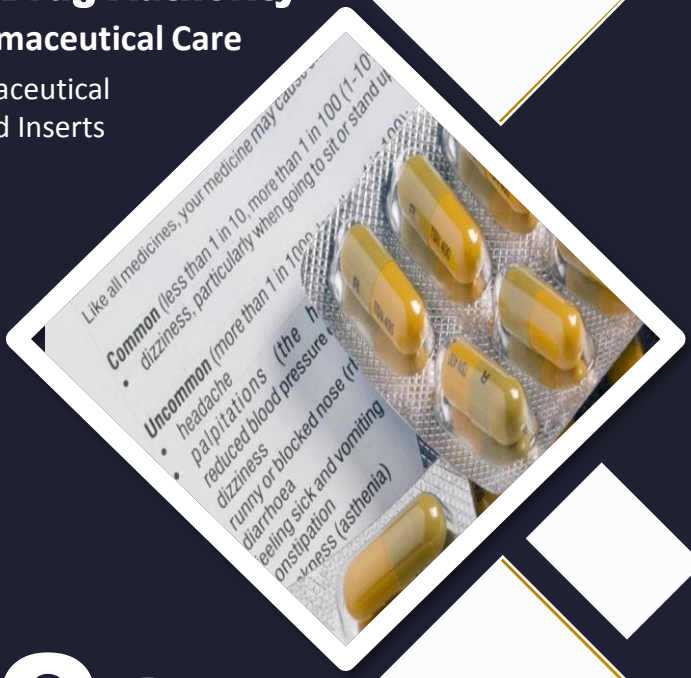
Egyptian Drug Authority

C A for Pharmaceutical Care

G A for Pharmaceutical
References and Inserts



FAQs

For Medical Inserts Administration

edaegypt.gov.eg

insert @edaegypt.gov.eg

Preface

Emerging from the keenness of the General Administration of Pharmaceutical References and inserts for continuous development and fruitful communication with Market authorization holders.

Medical Inserts department has the honor to present this booklet endorsing the most common frequently asked questions, the department has received lately, so as to be a guidance for Market authorization holders.

Special thanks to **Dr.Tamer Essam**, Head of the Egyptian Drug authority, **Dr. Shereen AbdelGAwad** Head of the General Administration of Pharmaceutical Care for continuous support for this document to come to light.

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Glossary

Type of request	Definition
Under registration تحت التسجيل	هو التقدم للحصول على نشرة معتمدة جديدة ضمن اجراءات التسجيل وفقا لنظام التسجيل It is to apply for a new approved insert within the registration procedures under any registration system
Tentative to final من مبدئي لنهائي	هو التقدم للحصول على نشرة معتمدة حديثة ضمن اجراءات الحصول على اخطار نهائي سواء قبل التقدم للحصول على أخطار او بعد الحصول على تحويل من القسم المختص بتحديث النشرة It is to apply for an updated approved insert as part of the procedures for obtaining a final license, whether before applying for getting a license or after obtaining a transfer from the particular department concerned with updating the insert
Re-registration إعادة تسجيل	هو التقدم للحصول على نشرة معتمدة حديثة ضمن اجراءات إعادة التسجيل بعد الحصول على موافقة ثبات إعادة التسجيل أو بعد التحويل من القسم المختص لتحديث النشرة It is to apply for an updated insert within the re-registration procedures after obtaining the stability approval of re-registration or after transferring from the particular department to update the insert
Warning addition أضافة التحذيرات	وهو التقدم بالنشرة المعتمدة سابقا لأضافة التحذيرات الصادرة من اللجنة الفنية لمراقبة الأدوية ولجنة الفارماكولوجي سواء المحددة بمهلة معينة أو عند التسجيل واعادة التسجيل It is the submission of the previously approved insert to add warnings issued By Technical Or Pharmacology Committee, whether specified by a specific deadline or upon registration and re-registration

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Type of request	Definition
Replacement Insert بدل الفاقد	هو التقدم للحصول على صورة طبق الاصل من النشرة المفقودة من قبل الشركة It is to apply for a copy of the missing insert by the company
Appeal الألتماس	هو طلب مقدم من قبل الشركة بخصوص امر ما يخص النشرات يعرض على اللجنة المختصة سواء اللجنة الفنية او الفارماكولوجي مثل: (طلب بخصوص اضافة التحذيرات بداخل النشرة، تطبيق النشرات المحدثة، أو أي موضوع فني يتعلق بالمستحضر يتطلب العرض علي اللجنة. It is a request submitted by the company regarding a matter related to bulletins that is presented to the competent committee, whether the technical or pharmacological committee, such as: (a request regarding adding warnings within the insert, applying the updated inserts, a request regarding the reference or Any technical issue requiring Committee decision
Update التحديث	هو التقدم لتحديث نشرة معتمدة سابقا لأسباب تخص مأمونية الدواء It is to apply to update a previously approved insert for reasons related to the safety of the medicinal product or addition of a new indication
Variations المتغيرات	It is to apply to change or update some parts of the previously approved insert according to the variation approval issued by the particular department. • Variations Requiring insert update e.g.: 1-Dosage form 2-Equivalence 3-Excipients (requires warning addition) 4-Naming 5-Tablet scoring 6-Route of administration

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Q Where can I find the lactose warning?

A: You can find Lactose warning in Pharmacology Warnings Sheet. The link of the sheet is on Pharmacology Submission Google Form.

Lactose warning for oral dosage forms:

In SmPc:

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

In PIL:

لا تتناول هذا الدواء إذا أخبرك طبيبك أنك لا تتحمل بعض أنواع السكريات.

Q I have received an acceptance email. Why cannot I find my leaflet in approved leaflets sheet?

A: Acceptance e-mail confirms the eligibility of the submitted file for the assessment process according to the Pharmacology Department declared requirements.

Acceptance e mail does not confirm the approval of the submitted leaflet.

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Q **Please consider the following for correct leaflet submission either as a new submission or a correction.**

- In case you have received a **refusal** e-mail, the requirements should be fulfilled and re submitted the following Week on **Pharmacology submission link.** https://forms.gle/dx5c8LJWbv1P8fw27

- In case you have received a **correction** e-mail , corrections required should be amended and submitted on **Pharmacology correction link** the following week https://docs.google.com/forms/d/e/1FAIpQLSf_Dcml_zBn_0zXEZk4ejjBU1q7ny9vhp5hQBSOX4tKjayhUw/viewform

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Q What is the status of my leaflet?

A: Please use the following link to find your leaflet status:
https://docs.google.com/spreadsheets/d/1SEX2GJuFXkIwd_3EZpc1N6gxuq9BK0ixBhd2As0_FIc/edit?usp=sharing
The above link is weekly updated every Monday. A workbook of two searchable Excel sheets: Approved leaflets & Correction leaflets are displayed.

Q I found my leaflet in correction sheet but I have not received a correction inquiries email. Why?

A: Some technical problems hinder receiving or sending emails. Make sure that your email address is right. You can communicate your inquiry by telephone or to the reception pharmacist as well.

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Q Declaration letter template. Where can I find it?

Leaflet Declaration Letter

- We (License Holder), declare that the attached (leaflet Smpc or Pil or Smpc&Pil) of (Trade name) code (…), revision date(…) , is the most updated and currently marketed in the country of origin (…)
- For non-English leaflet: We commit that the medical leaflet is translated according to authorized medical translation on our responsibility in accordance with the translation attached.
- Company Signature & Stamp

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Q I have sent an email and got no reply. What else should be done?

A: Kindly be noted that there are five days period to respond to an email. If your inquiry is urgent you can communicate it through telephone or to the reception pharmacist.

Q How can I communicate with the department?

- Mail : inserts@edaegypt.gov.eg
- Reception:
  Monday : 11:00 a.m. to 12:00 p.m.
  Tuesday: 12:00 p.m. to 1:00 p.m.
- Internal line no. :**02- 2535410** extension:**1436**

Q I have not got a long-term stability approval yet. Why cannot I submit my leaflet for approval?

A: You can approve your leaflet without long term stability approval except if the leaflet approval is needed for re-registration of a product.

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Q **I have not made the subdivision test to prove the dose division criteria of my product tablet. Why cannot I approve my product leaflet as a scored tablet for dose division?**

A: The subdivision test is the only proof for dose division. In case you have to approve a leaflet in order to use a production batch to make the subdivision test, you use a scored tablet reference to approve the leaflet

Q **What is the procedure for applying to get an approved template that I can use for preparing my leaflet?**

A: you can send an email to ask for a template and attach the composition of your product, The department will send one When applicable.
Then you can submit your request for leaflet approval according to the requirements shown in Pharmacology Submission Google Form.

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Q

My product is a non-reference product. How can I make a leaflet for it?

Two steps for that:

1) An inquiry for a template for an approved leaflet for a similar product is sent via Pharmacology Department email.

If this not available:

2) **Use:**

- The authorized references for basic scientific information about the active ingredients like: side effects, contraindications, maximum dose, pregnancy and breast feeding.
- Supportive references:
  - ❑ Martindale
  - ❑ British National Formulary
  - ❑ Physician Desk Reference
  - ❑ Lexicomp
  - ❑ Micromedics
  - ❑ Vidale
  - ❑ Rote liste
  - ❑ Drugs.com
  - ❑ Medscape

Q What are the common warnings and important calculations for inactive ingredients?

➢ **Some important inactive ingredients calculations:**

The substance	Limits of the substance amount	The relevant warning statement if limits exceed
Sorbitol	Oral systemic: 10 g / day	Side effect: May cause softening of the stool.
Ethanol (which does not evaporate during process)	Internal dosage forms: less than 100mg-3g per dose.	In warning section: Be cautious when used in pregnant, breastfeeding, pediatrics, liver disease patients and epilepsy patients. In driving and using machines section: be cautious when driving or using machines.
Methylparaben (for all ages)	Oral systemic: 10 mg/Kg /day	Not allowed to exceed
Propylparaben (for all ages)	Oral systemic: 2 mg/kg/day	Not allowed to exceed
Combination of the methyl and propylparabens	Oral systemic: 10mg/kg/day	Not allowed to exceed

➢ Some important inactive ingredients calculations: (Continued)

The substance	Limits of the substance amount	The relevant warning statement if limits exceed
Propylene Glycol	Systemic - Neonates up to 28 days 1mg/kg/day - 1month up to 4 years 50mg/kg/day - More than 4 years 500mg/kg /day	Not allowed to exceed
Some important Black Box Warnings (in English and Arabic leaflets)		
Benzyl alcohol	Under the leaflet title	This product contain benzyl alcohol, not for use in neonates up to 4 weeks old
Dronedarone	Under the leaflet title	Increased risk of death, stroke and heart failure in patients with decompensated heart failure or permanent atrial fibrillation
Antipsychotics	Under the leaflet title	Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

➢ Some important inactive ingredients calculations: (Continued)

The substance	Limits of the substance amount	The relevant warning statement if limits exceed
Some important Black Box Warnings (in English and Arabic leaflets)		
Vildagliptin	Under the leaflet title or in the section of warning.	LFTs "liver Function test " (ALT & AST) should be performed prior to the initiation of treatment in order to know the patient's baseline value. Liver function should be monitored during treatment at three month intervals during the first year and periodically thereafter.