



هيئة الدواء المصرية

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The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلانية المصري

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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Local Alert: Sub-standardized and Falsified (SF) Product

Egyptian Drug Authority Alert Regarding Nexium 40mg Counterfeit

The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding presence of counterfeited Nexium 40mg 14 tabs & 28 tabs in the market. EDA is quarantining the counterfeited batches.

EDA distributed and published circular with all data concerning the counterfeited product and how to differentiate between the original and counterfeit packs on EDA's website ([Click here](#)).

The Egyptian Pharmaceutical Vigilance Center is encouraging public to report any detected packs through ([Click here](#)).

Original



Counterfeit



Egyptian Drug Authority Alert Regarding Vigamox 5mg/ml Eye Drops Solution Counterfeit

The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding presence of counterfeited Vigamox 5mg/ml Eye Drops Solution in the market. EDA is quarantining the counterfeited batches with numbers 22B24AA- 21J20BA.

EDA distributed and published circular with all data concerning the counterfeited product and how to differentiate between the original and counterfeit packs on EDA's website ([Click here](#)).

The Egyptian Pharmaceutical Vigilance Center is encouraging public to report any detected packs through ([Click here](#)).

Original



Counterfeit



Direct Healthcare Professional Communication (DHPC): Propofol – Reminder of Instructions for Safe Use

EPVC in agreement with marketing authorization holders (MAH) of products containing Propofol would like to inform you of the following:

Summary:

- * Propofol is for single use only.
- * Opened containers must be disposed of after use.
- * Any remaining residue of the content must be discarded and never reused by another patient.

Background on safety concern:

Propofol Indication:

- Propofol is approved for induction and maintenance of anesthesia in adults and children from 1 month.
- Sedation for diagnostic and surgical procedures in adults and children from 1 month
- Sedation of ventilated patients over 16 years of age in intensive care

Among other things; the following safety instructions (depending on the dosage form) must be strictly observed:

- ⇒ Before use, the rubber membrane of the vial should be cleaned with medicinal alcohol.
- ⇒ Propofol contains no antimicrobial preservatives and favors the growth of microorganisms.
- ⇒ The emulsion must be drawn aseptically using a sterile syringe and infusion set immediately after breaking the seal of the vial.
- ⇒ Administration must be started immediately.
- ⇒ Both the medicinal product and the infusion set must be kept aseptic throughout administration.
- ⇒ The duration of an undiluted propofol infusion from an infusion system must not exceed 12



NO preservatives!

- Aseptic preparation required
- Discard unused portion



hours, for diluted propofol infusions must not exceed 6 hours. After 12 hours or 6 hours; leftovers of propofol products must be discarded and the infusion system renewed.

- ⇒ The contents of the vial, as well as any syringe or infusion set used, containing propofol is for single use for an individual patient only. Contents remaining after use must be discarded.

Failure to comply with these requirements result in serious side effects. Serious side effects are side effects that are fatal or life-threatening or, for example, require hospitalization .

References: BASG ([Click here](#))



Local Case Report

Case Reports: Increased Reports of Hypersensitivity Adverse Drug Reaction in Egypt

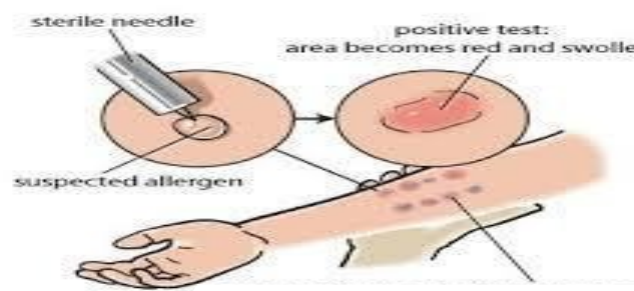
The Egyptian Pharmacovigilance Center received many reports of hypersensitivity adverse drug reactions from different drug formulations such as injections, tablets, and syrups for different age groups of Egyptian patients. An increase in the number of reports had been observed since 2020 was higher than that previously monitored, especially concerning antibiotics injections hypersensitivity.

In the context of Pharmacovigilance role in monitoring drug safety in the Egyptian market and through good communication during monitoring hypersensitivity reactions signals of different drug formulations, EPVC is providing an overview on hypersensitivity reactions and recommendations on drug handling and administration for community pharmacies, health care professionals, hospitals, and patients in order to maintain the safety of Egyptian patient.

Background:

Hypersensitivity reaction, acute systemic: : allergic reaction with wide spread effects such as shortness of breath, skin rashes and low blood pressure. A hypersensitivity reaction is an extreme or unnecessary immune response that the body has to an antigen. There are four different types of hypersensitivity reactions.

Immune responses: protect the body from damage by fighting off invasive substances and infections. Sometimes, however, the immune system produces undesirable responses by identifying harmless substances as harmful. This is called a hypersensitivity response. An antigen or allergen can refer to a toxic or foreign substance that causes an immune reaction. After detecting an antigen and perceiving it as a potential threat, the immune system mounts an immune response to dispose of it. The body can produce different types of hypersensitivity reactions, de-



pending on the antigen a person has exposure to and how the body responds to it.

Hypersensitivity Skin Test

Skin tests together with the history are the most readily available and useful diagnostic tools in evaluating drug hypersensitivity reactions. In many cases, skin tests allow the physician to avoid hazardous provocation tests. Skin tests have also been employed in order to identify patients at risk. Whereas for -lactam antibiotics, muscle relaxants, and iodinated contrast media (ICM), the value of skin tests has been proven in a large number of patients and standardized protocols exist, for many other drugs this still has to be addressed in multicenter studies with common protocols. ⁽⁵⁾

Skin tests are generally safe for adults and children of all ages, including infants. In certain circumstances, though, skin tests aren't recommended. The most common side effect of skin testing is slightly swollen, red, itchy bumps. These wheals may be most noticeable during the test. ⁽⁶⁾

Rarely, allergy skin tests can produce a severe, immediate allergic reaction, so it's important to have skin tests performed at an office where appropriate emergency equipment and medications are available ⁽⁶⁾.



Case Reports: Increased Reports of Hypersensitivity Adverse Drug Reaction in Egypt **Continued**

Recommendations for Pharmacists in Community Pharmacies :

1. Community pharmacies and licensed drug storage sites must obtain the drug from trusted and legal sources as obtaining the drugs from illegal sources may affect drug and patient safety, which leads to exposing the pharmacist to legal liability.
2. Patients should not administer antibiotics injections in community pharmacies.
3. Dispensing antibiotics should be based on physician's prescription only. The pharmacist should clarify to the patient all information related to the dose, duration, method of administration and inform the patient of the necessity of performing a hypersensitivity skin test before antibiotic administration if it is stated in the drug label.
4. Pharmacists Should be vigilant for pharmacovigilance newsletters, inspection releases, and warnings related to drug quality and counterfeiting on a regular basis through the EDA website ([Click here](#)) to reduce the effect of drug counterfeiting problems.

Recommendations for Healthcare Professionals :

1. Physicians should not exaggerate in prescribing antibiotics repeatedly and should provide patients with all information regarding the administration of antibiotics injections as it should be given in hospitals only after applying hypersensitivity skin test if needed.
2. Health care professionals should inform the patient about all information required for the safe use of the medicines.
3. Emergency first aid and life-saving medicines must be available in hospitals, in order to save patients' lives in case of severe hypersensitivity reactions or anaphylactic shock

Recommendations for Patients:

1. Patients should administer antibiotics only with a prescription and under the supervision of a physician.
2. The patients must administer antibiotic injections in the hospital only after performing hypersensitivity skin test for the required antibiotics under medical supervision.

References:

1. EMA ([Click here](#))
2. Medical news today ([Click here](#))
3. FDA ([Click here](#))
4. NCBI ([Click here](#))
5. Allergolyon ([Click here](#))
6. MayoClinic ([Click here](#))



EPVC News

Pharmacovigilance Training and Workshop on “Quality Matters”

The Egyptian Pharmaceutical Vigilance Center (EPVC) conducted a training session and workshop on pharmacovigilance titled “Quality Matters” at Alex medical training center, which was organized by the Egyptian drug authority for unified procurement medical supply and technology management (UPA). This was done in line with the center's vision and mission to promote pharmacovigilance and the culture of reporting side effects among healthcare professionals to promote the safe and effective use of pharmaceutical products.



100 pharmacists and physicians attended from Alexandria university hospitals, Qabbari hospital, Damanhour, and Damietta oncology centers.

The training included lectures and workshops on the basics of pharmacovigilance, its importance, and how to report adverse events, from ICSRs processing to the action taken by the authority. In addition, it provided information regarding the quality of medical products and substandard falsified medicines.

Together for Safe Medicine Initiative Progress

We are happy to celebrate the ongoing success of the EDA initiative "together for safe medicine," as we started 3rd wave training program on 19 September 2022 , 128 pharmacists from 126 community and hospital pharmacies shared in it; benefiting from practicing pharmacovigilance. The pharmacists sharing in the initiative sent 566 adverse drug reactions reports to Pharmacovigilance national database since 19 September 2022 till now.

EPVC is Extremely thankful to all participating pharmacists in the Initiative for their important role in increasing the ADRs reporting rate and detecting different drug hypersensitivity cases in the Egyptian Market in specific and also helping EPVC and Inspection department in traceability of suspected counterfeited products in the Egyptian market.



Egyptian Pharmaceutical Vigilance Center (EPVC) Decentralization Trainings for Raising Reporting Awareness

The Egyptian Pharmaceutical Vigilance Center (EPVC) is delighted to continue the decentralization training in coordination with the Expanded Programme of Immunization (EPI) in the Ministry of health.

The Training targeting the agents working in the coordinating immunization program to learn how to report using the national database reporting system as an expansion for the pharmacovigilance effort, improve the reporting system and provide an access for the institution on a strong database.



EPVC Tips On Pharmacovigilance

What are Direct Healthcare Professional Communications (DHPC)?

A direct healthcare professional communication (DHPC) is a letter used to directly inform healthcare professionals about new, important information about a medicinal product. It is delivered by marketing authorization holder to healthcare professionals.





One report counts

A call for reporting

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

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

Communication information

The Egyptian Drug Authority (EDA)

Pharmaceutical Care Administration

The Egyptian Pharmaceutical Vigilance Center (EPVC)



Address: 21 Abd El Aziz AlSoud Street. El-Manial, Cairo, Egypt, PO Box: 11451

Hotline: 15301

Fax: +202 – 23610497

Email: pv@edaegypt.gov.eg,

pv.followup@edaegypt.gov.eg

Reporting link: www.edaegypt.gov.eg

<https://sites.google.com/view/epvc-reporting/healthcare-professional-public-adverse-drug-event-reporting/reporting-other-adverse-drug-event-cases>



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