EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

The Egyptian Pharmaceutical Vigilance center

مركز اليقظة الصيدلية المصري

IN THIS ISSUE

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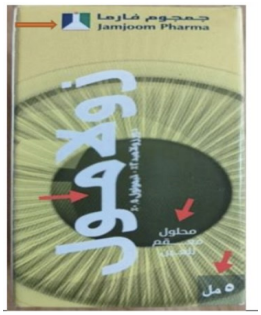
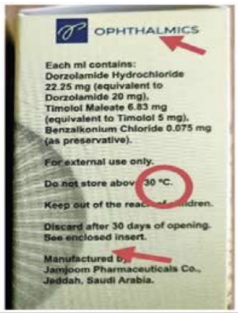
Local Alert: Sub-standardized and Falsified (SF) Product

Egyptian Drug Authority Alert Regarding Xolamol Sterile Ophthalmic Solution Counterfeit

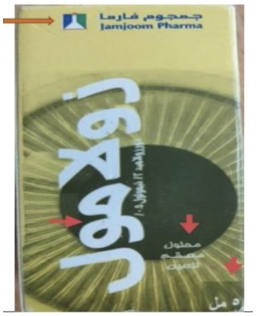
The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding the presence of counterfeited Xolamol sterile ophthalmic solution packs in the market. EDA started to quarantine the known counterfeited packs with batch number YG0158 .
EDA distributed and 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)*.

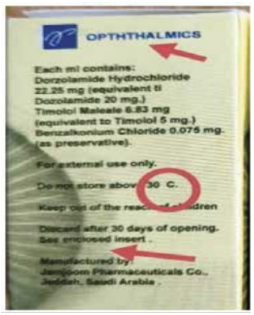
ORIGINAL





COUNTERFEIT





Commercial Fraud

Egyptian Drug Authority Alert Regarding Ivy cough Syrup & Ivermectin Lotion

The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding seizing and quarantining the following two products due to being not registered :

⇒ **Ivy Cough syrup**
Produced by: كرمان للصناعات الدوائية والكيماويات
Batch No.: 2021/1085

⇒ **Ivermectin 2% lotion 60ml**
Produced by: نويڤا كابيتال فارما
Batch No.: 2022/6241

Direct Healthcare Professional Communication (DHPC): Colchicine Serious Poisoning– Reminder of the Rules of Proper Use

EPVC in agreement with marketing authorization holders (MAH) of products containing Colchicine would like to draw your attention to the seriousness of colchicine poisoning, which is sometimes fatal, and to the rules to follow to reduce these risks :

Summary:

* Colchicine is a drug with a narrow therapeutic margin which exposes you to the risk of serious overdoses, the first signs of which are manifested by digestive disorders (diarrhoea, nausea, vomiting). Depending on the dose ingested, multivisceral failure, sometimes fatal, can occur (respiratory, cardiovascular, hematological, neurological damage, etc.)
* These risks which can be reduced by respecting the indications of the Marketing Authorization the dosage, the contraindications and the drug interactions

Background on safety concern:

Colchicine is indicated in the management of acute attacks of gout, in prophylaxis of acute attacks of gout in patients with gout chronic, in other microcrystalline attacks (chondrocalcinosis and hydroxyapatite rheumatism), in periodic disease, Behçet's disease and idiopathic pericarditis.

Instructions for prescribers and pharmacists:

- Comply with the dosage regimen recommended in the Marketing Authorization for each medicinal product;
- Reduce the dosage in the elderly (especially over 75 years old), hepatic insufficiency, renal insufficiency or subjects at risk of renal insufficiency (risk

of dehydration, concomitant medications) and ensure special monitoring of these patients;

- Respect the contraindications :
  - ⇒ in subjects with severe renal impairment (creatinine clearance < 30 ml/min)
  - ⇒ in severe hepatic impairment
- Check the risks of drug interactions
- Do not combine colchicine with pristinamycin and macrolides (except spiramycin) (combinations contraindicated);
- Inform patients of the importance of:
  - ⇒ adhering to the dosage;
  - ⇒ consult quickly in the event of the onset of diarrhoea, nausea, vomiting.

Dosage reduction or discontinuation should be considered

References: *EMA (Click here)*

Case Report from Cairo: Tigecycline - Medication Error

The regional center in Cairo received a case related to medication error with the use of Tigecycline & its details as follows: Male patient 24 years old received Tigecycline 50 mg by intravenous infusion for 3 days as an antibiotic which was considered medication error since it was administered without indication (Misuse of Tygaciline). The case was not serious.

Medical and past drug history were not mentioned.

Concomitant drugs for 3 days: Prednisolone (corticosteroids) 20 mg orally (2 tablets every 24 hours), Pantoprazole (Proton pump inhibitor) 40 mg orally once daily and Meropenem (Antibiotic) 500 mg by intravenous route once daily.

Background:

Medication error: a failure in the treatment process that leads to or has the potential to lead to a harm to the patient, The 'treatment process' involves all medications. [1]

Tigecycline: Tigecycline is the first drug in the glycylcycline class of antibiotics. Although it is structurally related to minocycline, alterations to the molecule resulted in its expanded spectrum of activity and decreased susceptibility to the development of resistance when compared with other tetracycline antibiotics. Tigecycline has a broad spectrum of activity, including activity against drug-resistant gram-positive organisms. Randomized trials have shown Tigecycline to be efficacious for the treatment of complicated intra-abdominal infections and complicated skin and skin structure infections. [2]

Labeled information:

- According to Tigecycline SPC section "Therapeutic indications":[3]

  Tigecycline is indicated in adults and in children from the age of eight years for the treatment of the following infections:

  * Complicated skin and soft tissue infections (cSSTI), excluding diabetic foot infections.
  * Complicated intra-abdominal infections (cIAI).

  Tigecycline should be used only in situations where other alternative antibiotics are not suitable.

  Consideration should be given to official guidance on the appropriate use of antibacterial agents.

- According to Tigecycline SPC section "Precautions": [3]

  In clinical studies in complicated skin and soft tissue infections (cSSTI), complicated intra-abdominal infections (cIAI), diabetic foot infections, nosocomial pneumonia and studies in resistant pathogens, a numerically higher mortality rate among tigecycline treated patients has been observed as compared to the comparator treatment. The causes of these findings remain unknown, but poorer efficacy and safety than the study comparators cannot be ruled out.

Case Report from Cairo: Tigecycline - Medication Error Continued

Recommendations for Patients and Healthcare Professionals:

1. Tigecycline should be used only in situations where other alternative antibiotics are not suitable [4].
2. Prescribing therapy in absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to patient and increases risk of development of drug-resistant bacteria[4].
3. There is an increased mortality risk with use of IV tigecycline[4]
4. Make sure that you give the medicine exactly as directed. That means: take the recommended dose according to the schedule on the label [5].
5. .You should to take the entire course of antibiotics. This means that if your doctor prescribes taking the medicine for 10 days, be sure to take it for the full 10 days, even if you are feeling better before then. If you stop taking the medicine early, some of the microbes may stay in your body and continue to multiply. This may cause another infection or mutate to a new form that could be resistant to future treatment. With some illnesses, complications can develop if the infection is not completely wiped out [5].
6. Ask your doctor whether you should be seen by him again after all of the prescribed antibiotics are taken [5].
7. If you haven't gotten better after taking the full course of antibiotics, be sure to let your doctor know. Your infection may be caused by germs that are resistant to the medicine he has taken[5].

Disclaimer: The method of case handling depends on the evaluation of the treating physician according to individual patient's need.

References:

1. *Oxford Academic (Click here)*
2. *NIH (Click here)*
3. *EMA (Click here)*
4. *Medscape (Click here)*
5. *Healthy children (Click here)*

Dermal Filler Do's and Don'ts for Wrinkles, Lips and More

People are seeking treatments to smooth smile lines and crow's feet and plump up their lips, cheeks, and hands. Injecting dermal fillers into the face and hands can improve the appearance of facial lines and volume loss caused by age or certain medical conditions.

In studies of dermal fillers approved by the U.S. Food and Drug Administration, people generally report they are satisfied with their treatment results. However, dermal fillers are not for everyone. Dermal fillers may not be appropriate for people with certain conditions, such as bleeding disorders or some allergies

What are dermal fillers?

Dermal fillers are gel-like substances injected under the skin. Dermal fillers are meant to create a smoother or fuller appearance, or both. The effects of most FDA-approved dermal fillers are temporary because they are made from materials that the body eventually breaks down and absorbs. The injection procedure may have to be repeated to maintain the desired effect .

Approved uses of dermal fillers

Dermal fillers are approved for specific uses in people aged 22 and older. Those uses include:

* Correcting moderate-to-severe facial wrinkles and skin folds
* Increasing fullness of lips, cheeks, chin, under-eye hollows, jawline, and back of the hand
* Restoring facial fat loss in people with human immunodeficiency virus (HIV)
* Correcting acne scars on the cheek

In reference to FDA; warnings about unapproved fillers

The FDA has not approved injectable silicone or any injectable fillers for body contouring or enhancement. The FDA has warned against getting filler injected into the breasts, buttocks, or spaces between the muscles. Using injectable filler for large-scale body contouring or body enhancement can lead to serious injury, including long-term pain, infection, permanent scarring or disfigurement, and even death.

The FDA has not approved needle-free devices for the injection of dermal fillers and warns against using them to inject hyaluronic acid or other lip and facial fillers. The injectors use high pressure and do not provide enough control over where filler will be placed. Serious injuries and in some cases, permanent harm to the skin, lips or eyes have occurred.

The FDA also warns against buying or using lip or facial fillers that are sold directly to the public.

Risks of approved fillers

As with any medical procedure, there are risks involved with the use of dermal fillers. Most side ef-

Dermal Filler Do's and Don'ts for Wrinkles, Lips and More Continued

fects reported in clinical trials and post-market surveillance occur shortly after injection and go away within a few weeks. In some cases, side effects may emerge weeks, months, or years later.

Common risks include:

- Bruising
- Redness
- Swelling
- Pain
- Tenderness
- Itching
- Rash
- Difficulty in performing activities (only observed when injected into the back of the hand)

People should be tested for allergies before receiving dermal fillers made with certain materials, especially materials derived from animals, such as collagen.

Unintended injection into blood vessels
The most serious risk associated with dermal fillers is accidental injection into a blood vessel. Filler that enters a blood vessel can cause skin necrosis (death of tissue), stroke, or blindness. While the chances of this happening are low, if it does happen, the resulting complications can be serious and may be permanent.

Tips for Consumers About Injectable Dermal Fillers:

1. Do work with a licensed health care provider who has experience in the fields of dermatology or plastic surgery and is trained to inject dermal fillers. The provider should use properly labeled, sealed vials or pre-filled syringes of approved filler.
2. Do request and read the patient labeling information on injectable dermal fillers from your licensed health care provider.
3. Do know the type of product to be injected and the possible risks. Know where each product you will be receiving is to be injected. Talk to your licensed health care provider if you have any questions.
4. Do not buy dermal fillers that are sold directly to the public. They may be fake, contaminated, or not approved for use.
5. Do not inject yourself with dermal fillers or with needle-free injection "pens."
6. Do not get any type of filler or liquid silicone injected for body contouring.

References: *FDA (Click here)*

For Reporting any Incident occurred from any Medical device, you can report through:

Serious incidents	Non serious incidents
• Through completing the form of **Pink user's incident report** • Electronically through : https://www.edaegypt.gov.eg/	Electronically through : https://www.edaegypt.gov.eg/
آثار جانبي الإبلاغ عن الآثار الجانبية للمستحضرات والمستلزمات الطبية	مخالفة الإبلاغ عن مخالفات تخص المستحضرات أو المنشآت الصيدلية

Pharmacovigilance Lecture in Collaboration with East Medical District Egyptian Ministry of Health and Population

In the context of the vision and mission of the Egyptian Pharmaceutical Vigilance Center (EPVC) in spreading awareness of pharmacovigilance and the culture of reporting side effects among healthcare professionals to promote the safe and effective use of pharmaceutical products, EPVC conducted training organized in collaboration with East Medical District; Egyptian Ministry of Health and Population.

The training consisted of two lectures; the first one was on the basics of Pharmacovigilance, its importance, how to report adverse events, other safety information, and a workshop. It was held on Wednesday 24 August 2022 in the lecture hall of Raml Pediatrics Hospital with 28 pharmacists from different healthcare units. The second lecture was titled "From Reporting to Actions with local and Global examples" held on Monday 29 August 2022 in the lecture hall of San Stefano Medical Center with 25 pharmacists attending.



Together for Safe Medicine Initiative Progress

We are pleased to announce the launching of the third wave of EDA initiative "together for safe medicine", registration was opened in August 2022 and the wave is expected to continue for three and a half months. This comes following the success of the first and the second waves which included 189 pharmacists from 185 pharmacies who are benefiting through practicing pharmacovigilance science in their community and hospital pharmacies, as displayed in the info graph below.

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 Kafr El-Sheikh Directorate and Chest Hospitals administration.

The Training was given during August 2022, by Cairo and Alexandria Regional centers as online lectures over two days then continued online training on the National database. The Training targeted pharmacists working in the coordinating institutions to learn how to report using the national database reporting system in accordance with the efforts to improve the reporting system and provide an access for the institution on a strong database.

EPVC Tips On Pharmacovigilance

What are generic drug products and Why Pharmacovigilance is needed for them?

Generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.

Although generic medications appear to be same as brand drugs, there can be differences based upon different manufacturers; thus pharmacovigilance is needed even for generics.

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)

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

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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