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

March 2023

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

Egyptian Drug Authority Alert Regarding Darzalex 400MG/20ML Counterfeit

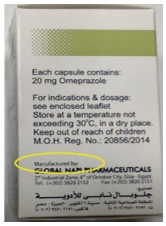
The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding presence of Darzalex 400MG/20ML VIAL in the market with Lot Number :LDS3E09 Expiry date: 03/2023 that does not belong to the drug market and is not distributed in the Arab Republic of Egypt.

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)*.

Egyptian Drug Authority Alert Regarding Napizole Counterfeit

Original



Counterfeit

The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding presence of counterfeited Napizole 20mg 14 caps in the market. EDA is quarantining the counterfeited batches with Lot numbers 120118 .

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)* .

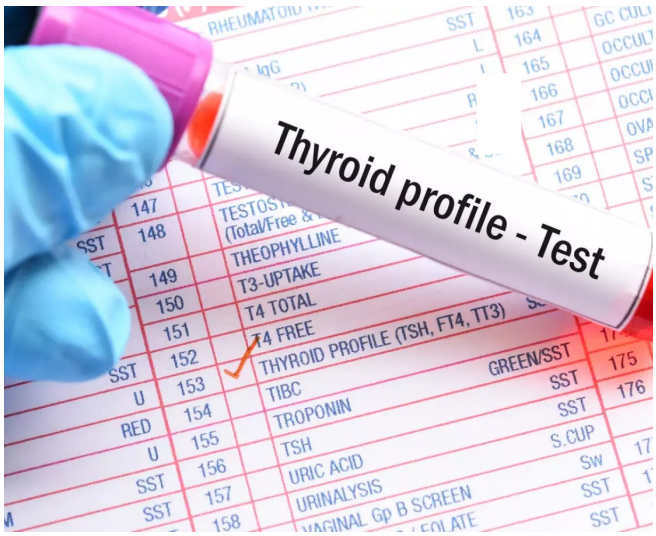
The Egyptian Pharmaceutical Vigilance Center is encouraging public to report any detected packs through *(Click here)*.

Direct Healthcare Professional Communication (DHPC): Levothyroxine containing products: Biotin interference with laboratory tests

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

Summary:

* Biotin may interfere with thyroid immunoassays that are based on a biotin/streptavidin interaction.
* These test methods are commonly used in clinical practice for the measurement of thyroid function tests and therapeutic drug monitoring for the adjustment of levothyroxine dosage.
* Depending on the assay design, test results may be falsely increased or falsely decreased. This may lead to inappropriate patient management or misdiagnosis.
* If results of thyroid function tests do not match the clinical presentation and/or other investigations, the possibility of biotin interference should be taken into consideration.
* Patients should be routinely asked about biotin use before ordering thyroid function tests. If a patient is taking biotin, inform the laboratory personnel before ordering the tests, alternative assays might be available.
* Patients should be advised to consult their doctor if they are taking or have recently taken biotin. They should also be made aware that, other products that they may take, such as multivitamins or supplements for hair, skin, and nails could also contain biotin and affect the results of their thyroid function tests.



Background on the safety concern & recommendations for Health care professionals:

⇒ Levothyroxine is a synthetic thyroid hormone that is authorized in adults and children for the treatment of a number of conditions associated with hypothyroidism, as well as in suppression therapy for thyroid carcinoma and for diagnostic use for thyroid suppression testing.

⇒ The interference of biotin with some immunoassays, can be explained by the role that exogenous biotin plays in disrupting the streptavidin-biotin interaction which is the basis of these immunoassays and hence leading to falsely decreased or falsely increased test results, depending on the assay format.

Direct Healthcare Professional Communication (DHPC): Levothyroxine containing products: Biotin interference with laboratory tests Continued

* Thyroid function tests evaluating the hypothalamic-pituitary-thyroid axis are conducted using immunoassays. Thyrotropin, free thyroxine and free triiodothyronine can be measured with sandwich or competitive assays. In a sandwich assay, the concentration of the substance being measured is directly proportional to the signal. In this case, extra biotin lowers the signal, causing falsely low values. In competitive immunoassays, the serum concentration of the particle measured is inversely proportional to the signal intensity, thus extra biotin levels cause falsely high values.
* Given the increasingly common use of biotin supplements in high dosage and the prevalence of hypothyroidism with dependence on periodic measurement of thyroid function tests for adjustment of T4 dosage, there is potential for clinical mismanagement of these patients based on misleading test results.
* In addition to this HCP communication, the product information (SmPC and package leaflet) of levothyroxine containing medicinal products will also be updated to reflect the risk of biotin interference with thyroid immunoassays.

Revised by:

Reem Hossam

References:

MHRA (Click here)

Case report from Cairo: Isotretinoin causing depression, skin dryness

The regional center in Cairo received a case report regarding a 28 years old female, weighs 60 kilograms suffered from acne.

Upon prescription she started to administer isotretinoin 20 mg orally three times per day for 7 months duration, with a cumulative dose nearly 12600 mg (193.8 mg per kg).

During the first month of isotretinoin administration, she developed depression, suicidal ideation, skin dryness and hair dryness. Isotretinoin was withdrawn after 7 months of administration, in consequence those adverse effects resolved after 2 months of drug discontinuation.

Patient was using concomitantly prednisolone orally for a total duration of 7 days within the first month of administering isotretinoin, and biotin orally. The reaction was considered non serious.

Background:

Oral isotretinoin is a retinoid that counteracts acne vulgaris. It is the only acne medication that combats all four factors in acne pathogenesis (ie, sebum production, follicular hyper keratinization, inflammation, and C. acnes). [4]

Proper use: Oral isotretinoin is a widely used treatment for nodular acne that is severe and stubborn. It is also used in clinical practice for less severe acne that is resistant to other medications or is accompanied by scarring. Isotretinoin cannot be used as a standard first-line treatment for mild, uncomplicated acne due to the potential of side effects, including teratogenicity.

Isotretinoin !!

Labeled Information: Summery of Product Characteristics (SPC):

Isotretinoin dose:

0.5 mg/kg/day in 2 divided doses for 1 month, then increase to 1 mg/kg/day in 2 divided doses as tolerated; alternatively, may administer the total daily dose once daily to increase adherence to therapy.

Adverse Reactions:

Psychiatric effects:

Isotretinoin may cause depression, psychosis, mood disturbance, and rarely, suicidal ideation, suicidal tendencies, death by suicide, aggressive behavior. Symptoms often resolve with therapy discontinuation

Skin and Appendages:

Eruptive xanthomas, flushing, skin fragility, hair abnormalities, hyperpigmentation, alopecia (which in some cases persists), cheilitis (dry lips), dry mouth, dry nose, and dry skin.

Case Report from Cairo: Isotretinoin causing depression, skin dryness Continued

Recommendations for Healthcare Professionals:

Dosing:

For patients with severe inflammatory acne (e.g., acne conglobata) or deep comedonal acne, consider initial doses <0.5 mg/kg/day (e.g., 0.1 mg/kg/day) in combination with an oral glucocorticoid given before or at isotretinoin initiation and continued for the first 2 to 4 weeks of therapy to reduce the risk of severe acne flares. Continue until a total cumulative dose of 120 to 150 mg/kg is reached.

The specific daily dose will determine how long the treatment will last. Usually, a 16–24 weeks treatment program is enough to induce remission.

What patients should know while taking isotretinoin:

Avoid prolonged exposure to UV rays or sunlight while taking this medication.

Due to the risk of scarring, skin rejuvenation procedures (e.g., dermabrasion, laser) and waxing should be avoided during treatment and for at least 6 months after discontinuing isotretinoin.

Patients should be advised to use skin moisturizing ointment or cream and a lip balm from the start of treatment as isotretinoin is likely to cause dryness of skin and lips.

Do not get pregnant while taking this medicine and for 1 month after stopping it. Women must have a negative pregnancy test twice before starting this drug and once monthly during treatment, even if they are not sexually active. Use two reliable methods of birth control 1 month before, during and after using isotretinoin.

Do not donate blood during taking isotretinoin or for 30 days after stopping it.

Isotretinoin may increase blood sugar level, consult your physician if you have diabetes about any modification in medication or diet.

Administer standard formulation with a meal; lidose or micronized formulations may be taken without regard to meals. According to the manufacturer's labeling, capsules should be swallowed whole with a full glass of liquid; do not chew or suck on the capsule.

Interactions, risk rating X: avoid combination:

Tetracyclines: The development of pseudotumor cerebri (also known as intracranial hypertension) is of particular concern

Multivitamins/Fluoride (with ADE): May enhance the adverse/toxic effect of Retinoic Acid Derivatives.

Multivitamins/Minerals (with ADEK, Folate, Iron): May enhance the adverse/toxic effect of Retinoic Acid Derivatives.

Multivitamins/Minerals (with AE, No Iron): May enhance the adverse/toxic effect of Retinoic Acid Derivatives.

Vitamin A: May enhance the adverse/toxic effect of Retinoic Acid Derivatives

Revised by:

Ola Fahmy

References:

1. *Monograph:* (Click here)
2. *Isotretinoin SPC :* (Click here)
3. *Background* (Click here)

Together for Safe Medicine Initiative Progress

We are happily announcing the success of the first three waves of the initiative [Together for safe medicine]. The third wave ended in March 2023. We are planning to start the fourth wave latterly.

The participating pharmacists in 3rd wave of EDA Initiative "Together for Safe Medicine " had made a lot of valuable activities as posts on social media, banners, videos and preparing training materials (PowerPoint, word, and PDF) aiming to improve their role in applying, practicing, and spreading the science of Pharmacovigilance between HCPs in the hospital pharmacies and public where they succeeded in spreading the meaning and aim of Pharmacovigilance to children and adults by making creative, attractive and simplified videos and by good communication with the public through their community pharmacies.

All the details and link for registration will be available and shared on EDA official page on Facebook as soon as possible.

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

The decentralization program is still going, and the Egyptian Pharmaceutical Vigilance Center (EPVC) is delighted to note that the number of reports received through the national database has been growing significantly.

As they continue to be the most cooperating organizations, we would like to express our gratitude to The Expanded Program of Immunization (EPI) and Specialized Medical Centers (SMCegy), in particular :

Qena Cancer Center, Nasser Institute, and Damanhour Oncology Center.

EPVC appreciate them and wishes them well going ahead for their efforts.

Revised by:

Ola Fahmy

The Egyptian Pharmaceutical Vigilance center
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EPVC Tips On Pharmacovigilance

Over use of Antibiotics cause Resistance

Antibiotic overuse is when antibiotics are used when they're not needed.

The overuse of antibiotics in recent years means they're becoming less effective and has led to the emergence of "superbugs". These are strains of bacteria that have developed resistance to many different types of antibiotics These types of infections can be serious and challenging to treat, and are becoming an increasing cause of disability and death across the world.

The biggest worry is that new strains of bacteria may emerge that cannot be treated by any existing antibiotics.

Visit EDA website to find all any 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*

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One report counts

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

A call for reporting

Please remember that you can report safety information of medicines to EPVC

Communication information

The Egyptian Drug Authority (EDA)
Pharmaceutical Care Administration
The Egyptian Pharmaceutical Vigilance Center (EPVC)

The Egyptian Pharmaceutical Vigilance center
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https://sites.google.com/view/epvc-reporting/healthcare-professional-public-adverse-drug-event-reporting/reporting-other-adverse-drug-event-cases

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