هيئة الدواء المصرية

IN THIS ISSUE

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The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية 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

August 2023

Volume 14 **Issue 8**

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

Egyptian Drug Authority Alert Regarding Viagra 100 mg Counterfeit

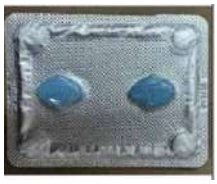
The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding presence of counterfeited Viagra 100 mg tablets in the market with batch number 3148002 . EDA is quarantining the counterfeited batches.

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 Exforge HCT Counterfeit

The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding presence of counterfeited Exforge HCT in the market. EDA is quarantining the counterfeited batches with Lot numbers B59ZX4 , BDPV3 , BDPW8

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

IDENTIFIED THREAT: FALSIFIED VERSIONS OF GLUCAGON-LIKE PEPTIDE 1 RECEPTOR AGONIST (GLP-1-RA) PRODUCTS

There has been a recent surge in demand for, and reported shortages of, GLP-1-RA products indicated to manage diabetes type II, which are also sought for weight loss.

- The World Health Organization (WHO) has received several reports of falsified GLP-1 receptor agonists. It is possible that falsified versions are sold and distributed through unregulated outlets, including social media platforms .
- Healthcare professionals and members of the public should be reminded of the risks of procuring medical products from unauthorized sources, including online.

Background and driving forces :

• Glucagon-like peptide 1 receptor agonist (GLP-1-RA) are a class of pharmaceuticals indicated to manage diabetes type II, which are also sought for weight loss. They are marketed globally under a variety of brands. These products should be procured with a medical prescription.

Since late 2022, global demand for GLP-1-RA products has risen, with reported shortages adversely impacting people living with diabetes type II. Shortages and irrational use may create environments favourable to falsified medical products.

There has been a surge of online information promoting the use of GLP-1 RA products for weight loss, encouraging risky procurement behaviours. Numerous online sources offer GLP-1 RA products for sale, without requiring a prescription. The quality and safety of medical products distributed in poorly controlled environments (such as the internet) cannot be assured.

Reports to WHO of falsified GLP-1-RA products have spiked in the past six months. It is possible that several versions of falsified GLP-1 RA – regardless of brand name – are in circulation.

Drug Safety Update

IDENTIFIED THREAT: FALSIFIED VERSIONS OF GLUCAGON-LIKE PEPTIDE 1 RECEPTOR AGONIST (GLP-1-RA) PRODUCTS (Continued)

Threats to public health

From Falsified products: Falsified medical products have been known to lack efficacy and/or cause toxic reactions. They are neither approved nor controlled by competent authorities and may have been produced in unhygienic conditions by unqualified personnel, contain unknown impurities, and are sometimes contaminated with bacteria.

from Shortages: People living with diabetes type II who miss treatment due to unavailability of GLP-1-RA products may suffer clinical consequences.

Preventive measures

Awareness raising: Competent authorities are requested to communicate to healthcare professionals, patients, and consumers in their country about the risks of:

i. procuring medical products from unauthorized channels;

ii. unsupervised consumption of GLP-1-RA products;

iii. shortages and the need to foresee mitigation measures, including alternative treatment options, in particular for people living with diabetes type II.

Healthcare professionals should comply with good prescribing and distribution practices. In many countries, it is legal to purchase medical products from properly authorized online pharmacies. The public should have adequate information to safely procure necessary medical products from authorized sources.

Supply chain oversight: Proactive market surveillance of GLP-1 receptor agonists offered through unauthorized channels is recommended. Promotion of these products on social media platforms should be considered a risk. Public authorities should liaise with platform owners in order to take down illicit sources of medical products. Relevant governmental authorities (such as, health authorities and law enforcement agencies) are encouraged to collaborate and share relevant information, as necessary and appropriate, to protect public health.

Monitor and notify shortages: All relevant supply chain actors should proactively monitor the availability of GLP-1 receptor agonists. Shortages should be notified to the competent authorities with accurate and detailed information.

Fever, Vomiting, Difficulty breathing, Tachycardia and Cyanosis associated with Immunoglobulin human normal.

The regional center in Cairo received a case of fever, vomiting, Difficulty breathing, Tachycardia and Cyanosis with the use of Immunoglobulin human normal, its details as follow:
A female patient with medical history of immunodeficiency with no other known medical or drug history conditions. The patient has not received any previous medications.
She received Immunoglobulin human normal after the administration of her usual dose, the patient began to exhibit signs and symptoms including fever, vomiting, tachycardia, cyanosis, and difficulty breathing.
Concerned about the severity of her condition, healthcare providers swiftly transferred the patient to the Intensive Care Unit (ICU) to provide life-saving medical interventions.
Medication was stopped and the patient remained in the ICU for nearly four days, it was a Life-threatening serious case.

Background:

Immunoglobulin human normal is a replacement therapy for primary and secondary immunodeficiencies, and IgG antibodies against bacteria, viral, parasitic and mycoplasma antigens; interference with Fc receptors on the cells of the reticuloendothelial system for autoimmune cytopenias and ITP; provides passive immunity by increasing the antibody titer and antigen-antibody reaction potential, so it is used in the following:
Antiviral prophylaxis
Chronic inflammatory demyelinating polyneuropathy.

Dermatomyositis/Polymyositis, severe, life-threatening, or refractory.
Hypogammaglobulinemia, prophylaxis against bacterial infection.
Immune thrombocytopenia.
Kawasaki syndrome.
Multifocal motor neuropathy.

The dose and Method of administration

Should only be administered intravenously. Other routes of administration have not been evaluated.
The dose and dose regimen is dependent on the indication.
The dose may need to be individualized for each patient dependent on the clinical response. Dose based on body weight may require adjustment in underweight or overweight patients.
In adults, calcium acetate binds phosphorus more effectively than calcium carbonate, while reducing the frequency of hypercalcemic events .

Fever, Vomiting, Difficulty breathing, Tachycardia and Cyanosis associated with Immunoglobulin human normal. (Continued)

Immunoglobulin human normal 50 mg/ml should be infused intravenously at an initial rate of 0.01 - 0.02 ml/kg/min for the first 20 to 30 minutes. In case of adverse reaction, either the rate of administration must be reduced, or the infusion stopped. If well tolerated, the rate of administration may gradually be increased to a maximum of 0.1 ml/kg/min.

Summary of the safety profile

Chills, headache, dizziness, fever, vomiting, allergic reactions, nausea, arthralgia, low blood pressure and moderate low back pain.

Reversible haemolytic reactions; (rarely) haemolytic anaemia requiring transfusion.

(rarely) a sudden fall in blood pressure and, in isolated cases, anaphylactic shock, even when the patient has shown no hypersensitivity to previous administration.

(rarely) transient cutaneous reactions (including cutaneous lupus erythematosus - frequency unknown)

(very rarely) thromboembolic reactions such as myocardial infarction, stroke, pulmonary embolism, deep vein thromboses

Cases of reversible aseptic meningitis

Cases of increased serum creatinine level and/or occurrence of acute renal failure

Contraindications

Hypersensitivity to the (human immunoglobulins) or to any of the excipients.

Fructose intolerance.

In babies and young children (aged 0 - 2 years) hereditary fructose intolerance (HFI) may not yet be diagnosed and may be fatal, thus, they must not receive this medicinal product.

Patients with selective IgA deficiency who developed antibodies to IgA, as administering an IgA-containing product can result in anaphylaxis.

Special warnings and precautions

Immediate anaphylactic and hypersensitivity reactions are a remote possibility. Epinephrine and antihistamines should be available for treatment of any acute anaphylactoid reactions.

Each ml of this medicinal product contains 50 mg of sorbitol. Patients with rare hereditary problems of fructose intolerance must not take this medicine.

In people more than 2 years old with HFI, a spontaneous aversion for fructose-containing foods develops and may be combined with the onset of symptoms (vomiting, gastro-intestinal disorders, apathy, height and weight retardation). Therefore, a detailed history with regard to HFI symptoms has to be taken of each patient prior to receiving Immunoglobulin human normal.

In case of inadvertent administration and suspicion of fructose intolerance the infusion has to be stopped immediately, normal glycaemia has to be re-established and organ function has to be stabilized by means of intensive care.

Potential complications can often be avoided by ensuring that patients:

Are not sensitive to human normal immunoglobulin by initially injecting the product slowly (at an initial rate of 0.01 - 0.02 ml/kg/min)

Are carefully monitored for any symptoms throughout the infusion period. In particular, patients naive to human normal immunoglobulin, patients switched from an alternative IVIg product or when there has been a long interval since

Fever, Vomiting, Difficulty breathing, Tachycardia and Cyanosis associated with Immunoglobulin human normal.

the previous infusion should be monitored at the hospital during the first infusion and for the first hour after the first infusion, in order to detect potential adverse signs. All other patients should be observed for at least 20 minutes after administration

In all patients, IVIg administration requires:

- adequate hydration prior to the initiation of the infusion of IVIg
- monitoring of urine output
- monitoring of serum creatinine levels
- avoidance of concomitant use of loop diuretics

In case of adverse reaction, either the rate of administration must be reduced, or the infusion stopped.

Traceability

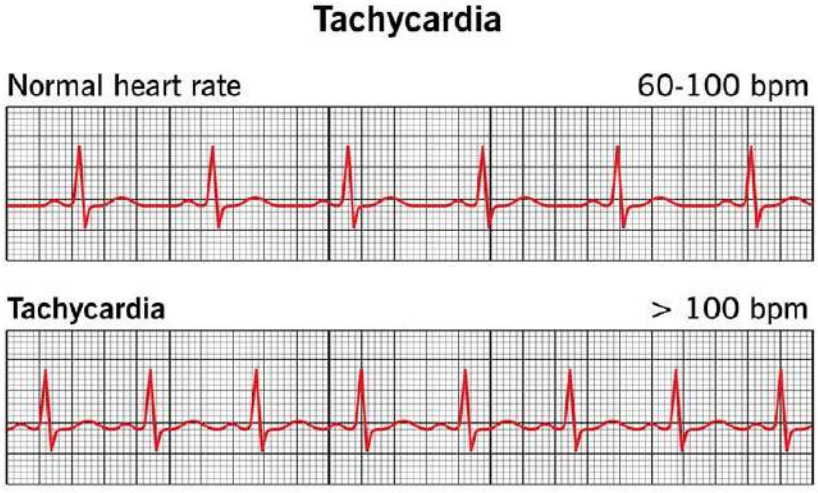
To improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

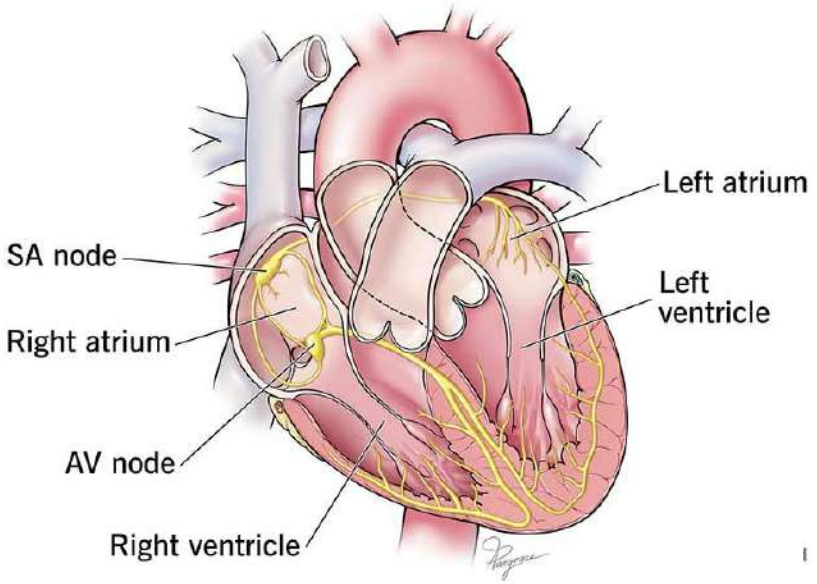
Special precautions for disposal and other handling

The product should be brought to room or body temperature before use.

The solution should be clear or slightly opalescent and colorless or pale yellow. Solutions that are cloudy or have deposits should not be used.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.





References:

1. ***EMA*:** (*Click here*)

Pharmacovigilance Awareness Campaign

As a crucial part of the Egyptian Pharmaceutical Vigilance Center's (EPVC) vision and mission to promote pharmacovigilance and foster a reporting culture among healthcare professionals, a training session on Pharmacovigilance was conducted in July 2023. The training aimed to encourage the safe and effective use of medicinal products available in the Egyptian market that involved the participation of several health Insurance Organizations (HIO) as well as Alexandria Urology Hospital.

During the training, the participants received a comprehensive presentation covering the fundamentals of Pharmacovigilance, its significance in healthcare, and the essential process of reporting adverse events and other safety-related data for various types of medicinal products.

EPCV would like to thank the
Egyptian Healthcare Authority at Port Said
for their good practice regarding reporting ICSRs and we are looking forward to more fruitful participation

Thank You!

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

Together for Safe Medicine Initiative Progress

EDA is extremely proud for the achievement of Initiative "Together for safe medicine "goals of the first three waves with the help of Egyptian pharmacists from all 27 governments all over Egypt where pharmacists showed great interest in learning, applying, practicing, spreading the science of Pharmacovigilance and increasing the ADRs reporting rate through their community and governmental Pharmacies. EDA rewarded the top achievers' pharmacists of the first three waves with a shield of distinction through a huge celebration as an appreciation for their valuable efforts.

The first three waves of activities started on 20 September 2022 till January 2023 and ended with a celebration and receiving a badge. The received badge is to be hung in shared pharmacies indicating their valuable sharing and practicing of Pharmacovigilance which will be renewed after two years provided that the shared pharmacies keeping in practicing Pharmacovigilance activity and send ADRs reports to the national database.

EPVC encourages all shared pharmacists to keep on and never stop sharing and sending ADRs reports because it is our honor to keep Sharing with us in EPVC Community Club and to keep in saving patients' lives through practicing pharmacovigilance.

Egyptian Pharmaceutical Vigilance Center (EPVC) Vigiflow expansion project Trainings for Raising Reporting Awareness

We are delighted to announce that the Egyptian Pharmaceutical Vigilance Center (EPVC) is continuing the Vigiflow Expansion training in collaboration with the Supreme Council of Universities Medicines Information Network (SCUMIN)

As part of our dedication to pharmacovigilance, this training program is designed to educate pharmacists working in coordinating institutions on the effective utilization of the national database reporting system for reporting purposes. Furthermore, it aims to improve the reporting system itself and grant the organization access to a robust database.

EPVC Regional Centers conducted training from 9 to 11 July 2023, comprising two days of online lectures, followed by an additional day of tutorials on the National Database.

Furthermore, as the training sessions progress, EPVC remains actively involved in receiving cases through the national database. We diligently review these cases, provide feedback to the coordinating organizations, and assess the necessity for further training. This ongoing endeavor seeks to enhance the quality of the cases entered into the database.

EPVC Tips On Pharmacovigilance

Be Mindful of Food & Medication Interactions:

When food and drinks interact with medication, the medication may not work sufficiently or the drug can become too powerful as the body has trouble handling it properly.

The Academy of Nutrition and Dietetics mentions these common examples of food and drug interaction:

Grapefruit juice interacts with several drugs and may affect the way the body metabolizes medication. Drugs that may interact with grapefruit juice include: some statins, antihistamines, thyroid medications, blood pressure medications, birth control pills, cough suppressants and medications that block stomach acids.

Blood-thinning medications can interact with leafy green vegetables, affecting the blood's clotting ability.

Natural black licorice may interact with certain blood pressure medications and blood-thinning medications.

Salt substitutes can interact with ACE inhibitors and digoxin.

Tyramine (found in foods such as aged meats and cheeses, hot dogs, and chocolate) can interact with some medications used to treat depression or Parkinson's disease.

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*

The Egyptian Pharmaceutical Vigilance center
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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 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.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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