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 Glivec 400 mg tablet Counterfeit

The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding presence of counterfeited Glivec 400 mg tablet in the market with batch number 8865M . 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 Jakavi 20 mg tablet Counterfeit

The Egyptian Drug Authority (EDA) through the Central Administration of Operations announced an alert regarding presence of counterfeited Jakavi 20 mg tablet 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)*.

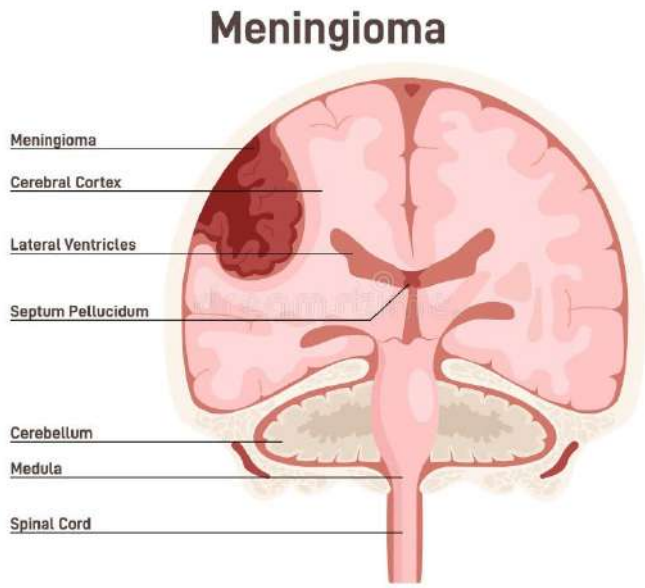
Original

Counterfeit

Safety Alert ! : Risk of meningioma and progestins: General Recommendations to limit this risk

Progestins are drugs used in various gynecological pathologies (endometriosis, fibroids, particularly long and/or heavy periods, cycle disorders), in hormone replacement therapy (including menopause); but also in obstetrics (sterility due to luteal insufficiency, repeated abortions). Between 2019 and 2020, successive epidemiological studies have demonstrated a risk of meningioma, which increases with the dose received, for three progestins (Androcur, Lutenyl, Luteran and generics). Following these studies, we then implemented numerous measures aimed at limiting this risk. As part of the enhanced monitoring that we carry out on all progestins, we have observed cases of meningioma occurring during treatment with other progestins .

The CST considers that a "class" effect of progestins on the risk of meningiomas cannot be ruled out and has established initial recommendations to limit this risk pending epidemiological studies, conducted by Epi-Phare, to confirm or negate this risk. The results of these studies should be available shortly. (CST) composed of representatives of people treated as well as health professionals to draw up recommendations on the conditions of use of progestins, other than those based on cyproterone acetate. (ACP), no megestrol (ANMG) and chlormadinone (ACM), with regard to the risk of meningioma. The aim was to ensure that the people fo whom this treatment is justified can continue to benefit from it under secure conditions



Among the cases of meningiomas declared under progestogen treatment, those reported with medrogestone (Colprone) and progesterone at 100 mg and 200 mg (Utrogestan and generics), are particularly suggestive of a role for these drugs given the stabilization or tumor regression on discontinuation of treatment. Thus, the summary of product characteristics (SPC) and the instructions for Colprone have just been updated in order to include the risk of meningioma. In addition, since progesterone 100mg and 200 mg are also used in the other countries of the European community, we have asked that this subject be the subject of a discussion

References:

1. ***ANSM*** (click here)

Two case reports from Alexandria: Concerning Intravenous infusion administration of Ampicillin Sodium and Sulbactam Sodium for two Neonates resulted in Serious adverse event to Neonates .

A 4 days neonate Female with a body weight of 2.6 Kg who Suffered from a Bacterial Chest infection and the Physician prescribed her (Ampicillin sodium, Sulbactam sodium) 750 mg vial by IV infusions to be diluted in 5 cm normal saline with a dose of 2.5 cm every 12 hr. the neonate started administration of (Ampicillin sodium, Sulbactam sodium) 750 mg with a dose as mentioned above and no ADRs occurred after the first 3 doses. on 27 March 2023 at 10 am the neonate received her fourth dose of (Ampicillin sodium, Sulbactam sodium) 750 mg vial with a dose of 2.5 cm with the rate of administration over 2 minutes by IV infusion. three minutes after the fourth dose the neonate suffered from Cardiac arrest which was a life-threatening Adverse event. The Physicians made Cardiopulmonary resuscitation and administered the neonate adrenaline, dexamethasone, Avil, and Solucortif ampoules and then they put the neonate on mechanical ventilation.

The Neonate was administered the following as concomitant Drugs: Cefotaxime sodium 500 mg vial by IV with a dose of 1.4 cm every 12 hr but the reporter did not suspect it as it was administered at another time and the reaction occurred immediately after (Ampicillin sodium, Sulbactam sodium) administration.

The reporter mentioned that the second case was a male neonate 8 days old who Suffered from a Bacterial Chest infection and administered 9 doses of (Ampicillin sodium, Sulbactam sodium) with no ADR and after administering of 10 th dose with a

dose of 2.5 cm of (Ampicillin sodium, Sulbactam sodium) on the same day and at the same time 10 am and **from the same vial which the first neonate** was administered as (vial was diluted in 5 ml water for injection and 2.5 cm administered for first neonate and the other 2.5 cm administered to the second neonate)and also he suffered from cardiac arrest as life-threatening Adverse event after 3 minutes of administration and he was saved by CPR, adrenaline, Avil and dexamethasone and he was put on Mechanical ventilation for 2 days and then recovered and completed his treatment of chest infection with another type of antibiotic.

Two case reports from Alexandria: Concerning Intravenous infusion administration of Ampicillin Sodium and Sulbactam Sodium for two Neonates resulted in Serious adverse event to Neonates .(Continued)

The reporter doubted in a medication error **by using 15% potassium chloride as a solvent for antibiotic reconstitution instead of water for injection** or normal saline due to the look-alike between potassium chloride ampoule and water for injection ampoule (both are 5 ml plastic ampoules) which was not confirmed.

No drug interaction was found between (Ampicillin sodium, Sulbactam sodium) and Cefotaxime sodium.

Rapid IV administration for Potassium chloride can cause cardiac arrest.

Also there was an administration error where (Ampicillin sodium, Sulbactam sodium) SPC mentioned that IV administration should be administered over 10-15 min and it was administered by IV over 2 mins only as mentioned by a reporter.

Background:

Ampicillin and sulbactam: (1) The combination of ampicillin and sulbactam injection is used to treat certain infections caused by bacteria, including infections of the skin, female reproductive organs, and abdomen (stomach area). Ampicillin is in a class of medications called penicillin-like antibiotics. It works by stopping the growth of bacteria. Sulbactam is in a class of medications called beta-lactamase inhibitors. It works by preventing bacteria from destroying ampicillin. antibiotics such as ampicillin and sulbactam injection will not work for colds, flu, or other viral infections.

Using antibiotics when they are not needed increases your risk of getting an infection later that resists antibiotic treatment.

Potassium Chloride solution: (2) Potassium chloride is a potassium salt indicated for the treatment and prophylaxis of hypokalemia with or without metabolic alkalosis, in patients for whom dietary management with potassium-rich foods or diuretic dose reduction is insufficient

Bacterial Chest infection: (3) A chest infection is an infection of the lungs or airways. The main types of chest infections are bronchitis and pneumonia. most bronchitis cases are caused by viruses, whereas most pneumonia cases are due to bacteria. Certain groups of people have a higher risk of developing serious chest infections, such as babies and very young children.

cardiac arrest: (4) Cardiac arrest, sometimes called sudden cardiac arrest, means that your heart suddenly stops beating. This cuts off blood flow to the brain and other organs. It's an emergency and is deadly if not treated immediately. Cardiac arrest can also happen for many reasons, including:

Too high levels of potassium or magnesium, which could lead to a deadly heart rhythm and other causes.

Two case reports from Alexandria: Concerning Intravenous infusion administration of Ampicillin Sodium and Sulbactam Sodium for two Neonates resulted in Serious adverse event to Neonates .(Continued)

Ampicillin sodium, Sulbactam sodium:
Dosage and administration: (5)
For IV administration, the dose can be given by slow intravenous injection over at least 10 to 15 minutes or can also be delivered in greater dilutions with 50 to 100 mL of a compatible diluent as an intravenous infusion over 15 to 30 minutes.

Neonatal Medication Guideline Potassium Chloride: (6)
Rapid IV infusions may cause cardiac arrest and cardiac dysrhythmias.
Potassium chloride infusion when given too rapidly, even when appropriately diluted can be fatal and result in death. Death can occur as a result of receiving concentrated potassium chloride as a direct push injection. Cardiac arrest may occur when potassium chloride concentrate has been added to an infusion without mixing prior to administration
Medication Error: (7)
While there is no uniform definition of a medication error, The National Coordinating Council for Medication Error Reporting and Prevention defines a medication error as: *"any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."* However, there is no widely accepted uniform definition. Unfortunately, untoward medical errors and underreported medication errors result in significant morbidity and mortality.
Some taxonomies consider the source of the error: Drug utilization process errors from the administration, dispensing, or monitoring.
Types of Medication Errors: Administration errors include the incorrect route of administration, giving the drug to the wrong patient, extra dose, or wrong rate.
Causes of Medication Errors in these cases:
Incorrect Preparation
This error usually occurs with compounding or some other type of preparation before the final administration. An example is choosing the incorrect diluent to reconstitute.
Incorrect Rate
Most often occurs with medications that are given as IV push or infusions. This is particularly dangerous with many drugs and may result in significant adverse drug reactions. Examples include tachycardia due to rapid IV epinephrine or red man syndrome due to the rapid administration of vancomycin.

Special warning and Recommendation for healthcare professionals:

IV administration of Ampicillin sodium and Sulbactam sodium, the dose should be given by slow intravenous injection over at least 10 to15 minutes or can also be delivered in greater dilutions with 50 to 100 mL of a compatible diluent as an intravenous infusion over 15 to 30 minutes(5).

Two case reports from Alexandria: Concerning Intravenous infusion administration of Ampicillin Sodium and Sulbactam Sodium for two Neonates resulted in Serious adverse event to Neonates . (Continued)

Potassium Chloride IV administration should be slowly over 24 to 48 hours and avoid bolus infusions due to increased risk of severe complications and extravasation with monitoring Serum potassium levels every 1 to 4 hours during infusion (while acutely correcting low potassium level) and Continuous ECG monitoring. (6)

Instructions For HCP Should be taken into consideration When prescribing 'when required' controlled drugs: (7)

document clear instructions for when and how to take or use the drug in the person's care record

include dosage instructions on the prescription (with the maximum daily amount or frequency of doses) so that this can be included on the label when dispensed

ask about and take into account any existing supplies the person has of 'when required' controlled drugs.

Store products with look-alike packaging in different locations.

Before administration, verify that the medication's indication, dose, dosage form, and route of administration align with the patient's condition or diagnosis.

The administration of medications should be done with Expert HCPs

EDA had taken the proper actions and confirmed that the batch sample comply required chemical and physical specifications which indicate that no quality issue exist in the product So it was most probable a medication error issue.

One of the most essential roles of EPVC towards Egyptian community after detecting serious cases or clusters is to Assist and highlight the serious risks associated with Medication errors , along with our recommendations and warnings for health care professionals and patients trying to increase awareness, and education of HCPs for prevention of medication errors and saving lives of Egyptian citizens

References:

1. ***Ampicillin and sulbactam*** (click here)
2. ***Potassium Chloride*** ***(Click Here)***
3. ***Bacterial Chest infection*** (Click here)
4. ***Cardiac arrest*** (Click Here)
5. ***Ampicillin and sulbactam Summary of Product Characteristics*** (Click here)
6. ***Neonatal Medication Guideline Potassium Chloride*** (Click here)
7. ***Medication Error(Click here)***

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

We are pleased to announce that the Egyptian Pharmaceutical Vigilance Center (EPVC) is extending its Vigiflow Expansion training program in collaboration with the Central Administration of Pharmaceutical Affairs (CAPA).
In our ongoing commitment to pharmacovigilance, we organized a training day This training aimed to educate pharmacists working in coordinating institutions on the optimal utilization of the national database reporting system for reporting purposes. Additionally, it sought to enhance the reporting system itself, providing the organization with access to the national database "Vigiflow".
EPVC's active role in receiving and reviewing cases via the national database, as well as providing feedback to coordinating organizations, displays a dedication to pharmacovigilance continuous improvement. This strategy is anticipated to yield a more robust and dependable approach for tracking and addressing pharmaceutical safety concerns. Overall, these efforts by EPVC and CAPA are commendable and contribute to the safety and well-being of patients in Egypt by ensuring the quality and effectiveness of pharmacovigilance practices.

We extend our deep gratitude to the Obstetrics and Gynecology Hospital at Portsaid for their commitment and active involvement in pharmacovigilance practices and the reporting of ICSRs. We are sincerely thankful for their valuable contributions to this vital field of healthcare, and we look forward to their continued dedication to the pursuit of safer and more effective medicines. We deeply appreciate their essential role within our pharmacovigilance community.

EPVC Tips

On Pharmacovigilance

Keep a Record of Your Medicines

Keeping an accurate and up-to-date record or list of the medications you take can be a valuable precautionary measure. First, it helps you and your family remember all the medications you are taking. Next, it helps your doctors, nurses, and pharmacists make sure that the medicines prescribed for you can be taken safely together. This record becomes especially important if you ever require hospitalization since the healthcare team at the hospital will use your list to determine if the medicine should be continued during your stay. Finally, your doctor can determine if any illness or symptoms you experience are related to the

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
مركز اليقظة الصيدلية المصري

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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