EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

EPVC

The Egyptian Pharmaceutical Vigilance center

مركز اليقظة الصيدلية المصري

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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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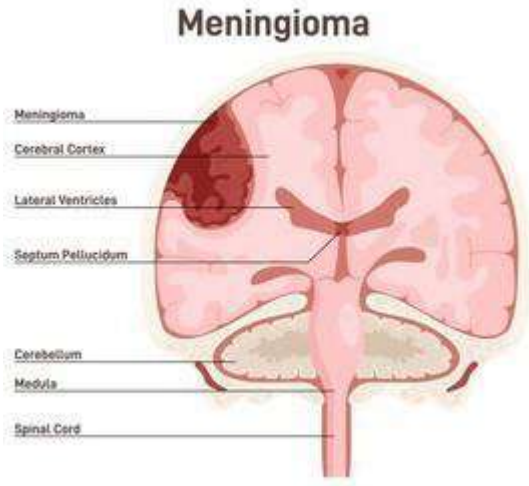
Safety Notification ! New recommendations to minimize the risk of meningioma with medicines containing medroxyprogesterone acetate

The European medicine agency (EMA) has published the following safety notification:

Key messages

Increased risk of meningioma seen in people taking high doses of medroxyprogesterone acetate for several years The PRAC has recommended measures to minimize the risk of meningioma, a type of brain tumor, with medicines containing medroxyprogesterone acetate. These medicines are used for gynecological (including contraception and endometriosis) and oncological indications. Meningiomas are tumors of the tissue layer surrounding the brain and spinal cord. Usually they are benign (noncancerous) and grow slowly but, depending on the size or location, they can cause serious problems. The committee's recommendations followed a review of data from epidemiological studies, case studies from the medical literature and cases reported in the pharmacovigilance database of the European Union. These data show an increased risk of meningioma in people taking high doses of medroxyprogesterone acetate (injectables and ≥100 mg tablets) for several years. Although the relative risk of meningioma is significantly increased with the use of high dose medroxyprogesterone acetate, the absolute risk is very small. PRAC recommended that, in patients who have a meningioma or have had one in the past, medicines containing high-dose medroxyprogesterone acetate must not be used, unless medroxyprogesterone acetate is needed for the treatment of an oncological indication. About Garcinia species

PRAC also recommended that patients taking high doses of medroxyprogesterone should be monitored for symptoms of meningioma, which can include change in vision, hearing loss or ringing in ears, loss of smell, headaches, memory loss, seizures and weakness in arms and legs. If a patient treated for a non-oncological indication is diagnosed with meningioma, treatment with high-dose medroxyprogesterone acetate must be stopped. If a patient treated for an oncological indication is diagnosed with meningioma, the need for further treatment with high-dose medroxyprogesterone should be carefully considered, on a case-by-case basis, taking into account individual benefits and risk



References:

EMA : *(Click Here)*

Safety Notification 2 ! Levofloxacin Incorrect drug administration rate medication error.

Case series reported to EPVC: about Levofloxacin Incorrect drug administration rate medication error.

The signal management department detected a case series reports of patients who used levofloxacin IV infusion with incorrect drug administration rate which resulted in some complications to the patients as follows: (hypotension, dyspnea, hypersensitivity, anaphylactic reactions, rash and headache)

Background:

Levofloxacin: is a fluoroquinolone antibiotic used to treat infections caused by susceptible bacteria of the upper respiratory tract, skin and skin structures, urinary tract, and prostate, as well as for post-exposure treatment of inhaled anthrax and the plague. [1]

Incorrect drug administration rate: is a type of medication errors which are the most common and preventable cause of patient injury. These errors typically involve administering the wrong drug or dose, using the wrong route or administering it incorrectly. The reported incidence of medication errors in acute hospitals is approximately 6.5 per 100 admissions. [2]

Labeled information of Levofloxacin solution for injection.

According to levofloxacin Summary of product characteristics (SMPc):

The usual dose of levofloxacin Injection is 250 mg or 500 mg administered by slow infusion over 60 minutes every 24 hours or 750 mg administered by slow infusion over 90 minutes every 24 hours.

Infusion precautions:

Levofloxacin injection should be administered for adult and pediatric patients by slow IV infusion over 60 minutes (250 to 500 mg) and over 90 minutes (for 750 mg).

Give by IV infusion only, not bolus; rapid or bolus administration has been associated with hypotension and must be avoided.

Avoid using IV line with solution containing multivalent cations (ie, magnesium, calcium). [3]

References:

1. ***What is levofloxacin :*** *(Click Here)*
2. ***What is incorrect drug administration rate:*** *(Click Here)*
3. ***IV Administration :*** *(Click Here)*

Local Case Report: Paclitaxel induced hypersensitivity reactions

Reason for publishing:

Since the beginning of 2024, the Egyptian Pharmaceutical Vigilance Centre has received 52 ICSRs of Paclitaxel-induced hypersensitivity reactions. 55.8 % of the reported ICSRs were serious, life-threatening and caused prolonged hospitalisation; death is reported as a possible outcome in one case.

Hypersensitivity and/or co-reported preferred terms (MedDRA)	
Dyspnoea	Reported in 22 cases
Erythema, and Pruritus	Reported in 10 cases
Bronchospasm and Flushing	Reported in 10 cases
Tachycardia	Reported in 4 cases
Cough and Hypotension	Reported in 3 cases
Anaphylactic reaction	Reported in 1 case

The following is one of those simple case scenarios:

A female patient of age 27-years-old and of weight 74 Kg, 145 Cm height, with no medical comorbidities, was diagnosed with triple-negative breast cancer (TNBC). She was planned to receive paclitaxel weekly protocol, her first cycle was on September 2, 2204.

Paclitaxel is the suspected active ingredient, the dose was 127.5 mg, Dexamethasone was a concomitant drug as a Chemotherapy premedication of a dose 8 mg. Also, Chlorpheniramine maleate is a concomitant drug as a Chemotherapy premedication of dose 5 mg. During the first minute of paclitaxel infusion, the case experienced redness of face, dyspnoea, tachycardia, and was diagnosed as a case of moderate hypersensitivity.

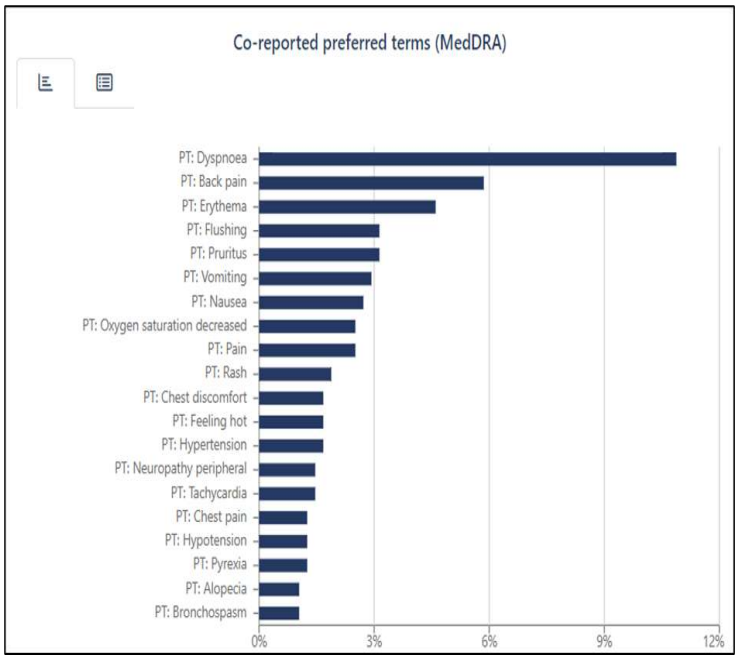
The corrective treatment included holding infusion for 1 hour, during which she received Hydrocortisone 100 mg vial ampoule intravenously, Chlorpheniramine ampoule intravenously, Ipratropium bromide nebulizer inhalation, oxygen mask as medical intervention to relief the symptoms.

The Adverse drug reactions recovered by treatment, she resumed her chemotherapy cycle with a slow rate of infusion and did not recur by the re-administration of the medication, and the chemotherapy protocol was continued, with no modifications. The reaction was considered serious because it was life-threatening and needed prolonged hospitalization.

Paclitaxel induced hypersensitivity reactions, VigiBase global view:

During the same period – January 2024 till now- the VigiBase received 478 ICSRs from more than 40 countries related to Paclitaxel induced hypersensitivity reactions, among those ICSRs the most common co-reported reactions are shown in the following figure

Background



The taxanes (paclitaxel, docetaxel and cabazitaxel) are widely prescribed anti-cancer drugs commonly associated with HSRs. These reactions are categorised as either immediate or non-immediate, and clinical presentations can vary from mild flushing and pruritus to severe anaphylaxis and death, nano-particle albumin bound-paclitaxel (nab-paclitaxel) whilst also a taxane, has a much lower incidence of HSRs compared to the other taxanes.

Incidence/prevalence

Mild HSRs are reported to occur in approximately 30-40% of patients being treated with taxanes, and severe HSRs in 1-4% of patients. While premedication is known to reduce reaction incidence and severity, reactions are not predictable and can occur despite premedication with corticosteroids and antihistamines. In the majority of cases, patients who experience a mild to moderate HSR can still be successfully treated with taxane therapy.

Local Case Report: Paclitaxel induced hypersensitivity reactions (continued)

Onset/duration

Immediate HSRs are those that occur during administration or within the first hour after administration. Symptoms generally develop within the first 10–15 minutes of an infusion and mild to moderate reactions will usually resolve after a brief interruption of treatment. In 95% of cases, these reactions occur during the first or second infusion. However, reactions can also occur with later infusions, even if they have not occurred with previous doses. Non-immediate HSRs can occur between one hour and several days after administration.

Immune system disorders	**Very common:** Minor hypersensitivity reactions (mainly flushing and rash) **Uncommon:** Significant hypersensitivity reactions requiring therapy (e.g., hypotension, angioneurotic oedema, respiratory distress, generalised urticaria, chills, back pain, chest pain, tachycardia, abdominal pain, pain in extremity, diaphoresis, and hypertension) **Rare**: Anaphylactic reactions **Very rare**: Anaphylactic shock **Not known**: Bronchospasm
Cardiac disorders:	**Common:** Bradycardia **Uncommon**: Cardiomyopathy, asymptomatic ventricular tachycardia, tachycardia with bigeminy, atrio-ventricular block and syncope, myocardial infarction **Rare:** Cardiac failure **Very rare:** Atrial fibrillation, supraventricular
Vascular disorders	Very common: Hypotension Uncommon: Hypertension, thrombosis, thrombophlebitis Very rare: Shock Not known: Phlebitis
Respiratory, thoracic and mediastinal	Rare: Dyspnoea, pleural effusion, interstitial pneumonia, lung fibrosis, pulmonary embolism, respiratory failure Very rare: Cough

Management of Paclitaxel induced hypersensitivity reactions:

A. Prevention of HSRs

Premedication to reduce of risk of hypersensitivity reactions of paclitaxel - 30 minutes before chemotherapy and intravenous medications include both H1- and H2-receptor antagonists, as well as dexamethasone; however, these do not eliminate the risk of HSRs entirely.

B. Treatment

Emergency treatment (e.g. adrenaline, antihistamine and corticosteroid) for severe HSR must be readily available during taxane administration.

If a patient develops an HSR, treatment should be stopped immediately and the symptoms treated with appropriate medication, for example, antihistamines, corticosteroids, bronchodilators and/or oxygen.

In many cases, a mild to moderate reaction will resolve after medication and a brief interruption of treatment. However, re-challenge can have potentially serious consequences, therefore administration of additional premedication, reducing the infusion rate and close monitoring during the next administration of the taxane is essential.

If the HSR presents as anaphylaxis, treat as per emergency procedure. Delays in emergency treatment are associated with an increased mortality rate.

References:

1. ***Paclitaxel SPCs:*** ***(Click Here)***
2. ***NHS Chemotherapy protocols:*** ***(Click Here)***
3. ***Eviq protocols:*** ***(Click Here)***
4. ***VigiLyze, qualitative view***

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

The Egyptian Drug Authority (EDA) is pleased to announce the holding of a training program for Egyptian Ministry of Health organizations/Focal Points on the Pharmacovigilance)

This training program aims to increase the awareness of the importance of reporting system to be with high quality, the Egyptian Pharmaceutical Vigilance Center (EPVC) is pleased to express gratitude and continue providing information on the national database through trainings that illustrate the framework for those organizations (The direct entry on Vigiflow database via expansion program).

Training program was Online.

The training program was offered to vigiflow Expansion Organizations (Ministry of Health).

"World Patient Safety Day News:

Alexandria pharmacovigilance center had celebrated World Patient Safety Day, on 17 September 2024 by organizing a lecture of introduction of Pharmacovigilance to health care professionals (HCPs) team of Ophthalmology hospital in Alexandria where 45 participants of pharmacists, physician and nurses attended. EPVC team member clarified to HCPs the role of pharmacovigilance science in safety of patient, drug safety in Egyptian market , the most recent techniques to report ADRs of pharmaceutical products as E-reporting link, Arabic link, Vigiflow accounts for shared hospitals in Expansion program. Also the role of Pharmacovigilance science in detection of safety signals for pharmaceutical products in Egyptian market had been clarified to attended HCPs.

EPVC Tips

On Pharmacovigilance

Optimizing Medication Adherence for Chronic Diseases

Medication adherence is crucial for managing chronic diseases effectively. By ensuring patients take their medications as prescribed, healthcare professionals can significantly improve patient outcomes and reduce the risk of complications. Here's a tip to help you optimize medication adherence:

Utilize technology-based solutions to enhance medication adherence.

Medication reminders: Employ smartphone apps, text message reminders, or wearable devices to help patients stay on track with their medication schedules.

Medication tracking: Use digital tools to monitor medication usage and identify potential adherence gaps.

Personalized adherence plans: Develop tailored adherence plans that consider patients' individual preferences, routines, and challenges.

By incorporating technology-based solutions into your practice, you can provide patients with the tools and support they need to adhere to their medication regimens and improve their overall health.

Visit EDA website to find all medicine- related news, updates and alerts Click here

You will find all EPVC Newsletters and DHPCs here

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One report counts

A call for reporting

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

Participate with us

We invite you to take a quick survey on how much our communication with you is effective
We value your feedback! Help us enhance our communication by taking a quick survey. Your insights are crucial in ensuring we meet your expectations.
Survey Link: (Click Here)

Thank you for your valuable input

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

Communication information

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