EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

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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Erythromycin: Update on Known Risk of infantile hypertrophic pyloric stenosis

Erythromycin is a macrolide antibiotic that is active against gram-positive cocci and gram-positive bacilli, some gram-negative cocci and some gram-negative bacilli. It is widely used to treat chest infections such as pneumonia, skin problems and sexually transmitted diseases.

Updates have been made to the magnitude of the known risk of infantile hypertrophic pyloric stenosis following exposure to erythromycin in infancy as a result of new epidemiological data. The risk is particularly increased in the first 14 days after birth.

Review of risk:

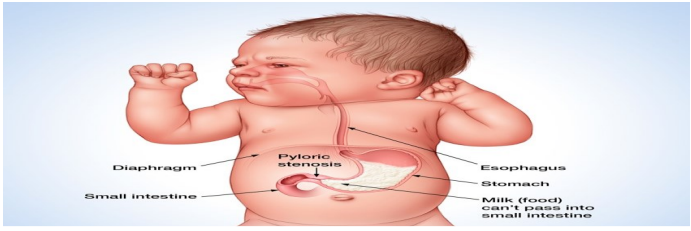
Erythromycin is used in children, often to treat ear or chest infections. Erythromycin is licensed for use in both adults and children (including infants and babies).

Infantile hypertrophic pyloric stenosis is characterised by hypotrophy and subsequent narrowing of the pylorus between the stomach and duodenum. Signs and symptoms in infants can include vomiting (sometimes forceful) and irritability after feeding. Treatment is usually pyloromyotomy, a surgical procedure where incisions are made in the muscle walls of the pylorus.

Use of the antibiotic erythromycin in infancy has been associated with an increased risk of infantile hypertrophic pyloric stenosis.

A recent European review of safety data assessed published literature studies, including data from three meta-analyses that support an association between exposure to erythromycin in infants and the risk of infantile hypertrophic pyloric stenosis.

The background incidence of infantile hypertrophic pyloric stenosis is thought to be 0.1–0.2% livebirths. The studies show that the risk of infantile hypertrophic pyloric stenosis following exposure to erythromycin is highest in the first 14 days after birth. Available data suggests an incidence of 2.6% (95% CI 1.5 to 4.2) for infants younger than 14 days following exposure to erythromycin.



Since erythromycin may be used in the treatment of conditions in infants that are associated with significant mortality or morbidity (such as pertussis or chlamydia), the benefit of erythromycin therapy should be weighed against the potential risk of developing infantile hypertrophic pyloric stenosis. Parents should be informed to contact their doctor if vomiting or irritability with feeding occurs.

In reference to MHRA; Advice for healthcare professionals:

* An increased risk of infantile hypertrophic pyloric stenosis following exposure to erythromycin in infancy has been reflected in the product information for some time
* Data from three recent meta-analyses has led to updates for the magnitude of increased risk with erythromycin use during infancy in general, and to reflect that the risk is highest in the first 14 days after birth
* Consider the benefit of erythromycin therapy against the potential risk of developing infantile hypertrophic pyloric stenosis
* Advise parents to seek advice from their doctor if vomiting or irritability with feeding occurs in infants during treatment with erythromycin

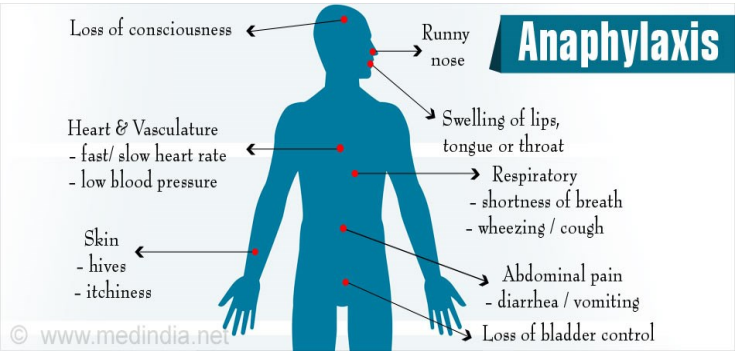
References:

MHRA (Click here)

Case Report from Menuofya: Ceftriaxone Serious Case of Anaphylactic Shock - Reminder of precautions for use to reduce the risk of hypersensitivity reactions

A serious case of anaphylactic shock was reported to Menuofya team after erroneous intramuscular (IM) administration of ceftriaxone 1 gm vial to a child without being pre-tested for hypersensitivity.

A six years old male child received ceftriaxone 1 gm intramuscularly for unspecified indication. After one minute of third dose administration, the patient developed signs of anaphylactic shock. He was transferred to hospital and received adrenaline ampoule but after 90 minutes of drug administration the child died.



Background :

Ceftriaxone is a semi-synthetic cephalosporin antibacterial agent for parental administration, indicated for infection known to be or likely to be caused by bacteria that are sensitive to ceftriaxone, this may include septicaemia, meningitis and chest infections such as pneumonia.

As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported.

EPVC would like to stress on the importance of following the precautions for use detailed in the product label to reduce the risk of such reactions, this includes performing a hypersensitivity testing before drug administration. It should be noted that hypersensitivity can appear with the first dose or with subsequent doses.

In case of severe hypersensitivity reactions, treatment with ceftriaxone must be discontinued immediately and adequate emergency measures must be initiated.

Labeled information:

According to Ceftriaxone Summary of product Characteristics (SmPC):

Method of Administration:

- For IV injection 1 g ceftriaxone is dissolved in 10 ml of water for injections PhEur. The injection should be administered over 5 minutes, directly into the vein or via the tubing of an intravenous infusion
- Ceftriaxone can be administered by intravenous infusion over at least 30 minutes (preferred route) or by slow intravenous injection over 5 minutes (preferably in larger veins), or by deep intramuscular injection.
- Intramuscular administration should be considered when the intravenous route is not possible or less appropriate for the patient. For doses greater than 2 g intravenous administration should be used.
- Diluents containing calcium, (e.g. Ringer's solution or Hartmann's solution), should not be used to reconstitute ceftriaxone vials or to further dilute a reconstituted vial for intravenous administration because a precipitate can form.

Ceftriaxone - Serious Case of Anaphylactic Shock: Reminder of precautions for use to reduce the risk of hypersensitivity reactions continued

- For pre-operative prophylaxis of surgical site infections, ceftriaxone should be administered 30-90 minutes prior to surgery.

Special warnings and precautions for use

Hypersensitivity reactions:

As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been re-ported. In case of severe hypersensitivity reactions, treatment with ceftriaxone must be discontinued immediately and adequate emergency measures must be initiated. Caution should be used if ceftriaxone is given to patients with a history of non-severe hypersensitivity to other beta-lactam agents.

While initially termed "warfarin-related nephropathy," we prefer the term "anticoagulant-related nephropathy" because the entity has been associated with anticoagulants other than warfarin.

Anaphylaxis Emergency

Anaphylaxis is a severe, life-threatening, generalized or systemic hypersensitivity reaction. It is characterized by rapidly developing, life-threatening problems involving: the airway (pharyngeal or laryngeal oedema) and/or breathing (bronchospasm with tachypnoea) and/or circulation (hypotension and/or tachycardia). In most cases, there are associated skin and mucosal changes.

In case of anaphylaxis, patients should be instructed to immediately seek help from the nearest medical facility:

* Patients with anaphylaxis should be assessed and treated as rapidly as possible, as respiratory or cardiac arrest and death can occur within minutes. Anaphylaxis appears to be most responsive to treatment in its early phases.
* The suspected drug should be stopped, cardiopulmonary resuscitation performed if needed. Some patients may need intubation.
* Epinephrine is lifesaving in anaphylaxis. It should be injected as early as possible in the episode to prevent progression of symptoms.
* Epinephrine can be injected intramuscularly (IM) with dose 0.01 mg/kg the mid-outer thigh in infants and children, the maximum is 0.5 mg per dose. For adults the dose is 0.3 to 0.5 mg.
* There are no absolute contraindications to epinephrine use in anaphylaxis, but it should be used with caution in elderly and only half the dose given in case the patient is using amitriptyline, imipramine or a beta blocker. The IM route is not recommended after cardiac arrest.
* According to the patient's condition, treatment may include oxygen, normal saline and bronchodilators. Adjuvant therapy includes: antihistamines and glucocorticoid.

Recommendations for Healthcare professionals :

1. Before beginning treatment, sensitivity test should be done; to ceftriaxone, to other cephalosporins or to any other type of beta-lactam agent.
2. Ceftriaxone can be administered by intravenous infusion over at least 30 minutes (preferred route) or by slow intravenous injection over 5 minutes (preferably in larger veins), or by deep intramuscular injection, Intramuscular administration should be considered when the intravenous route is not possible or less appropriate for the patient.
3. For neonates, intravenous doses should be given over 60 minutes to reduce the potential risk of bilirubin encephalopathy.
4. In infants and children up to 12 years of age, Doses of 50mg/kg or over should be given by slow intravenous infusion over at least 30 minutes. Doses greater than 80mg/kg body weight should be avoided because of the increased risk of biliary precipitates.
5. Ceftriaxone is contraindicated in premature neonates up to a postmenstrual age of 41 weeks (gestational age +chronological age) and full-term neonates at risk of developing bilirubin encephalopathy.
6. If lidocaine is used as a solvent, the resulting solution should never be administered intravenously; only intramuscular. The solution should be administered by deep intramuscular injection. Doses greater than 1g should be divided and injected at more than one site.
7. Diluents containing calcium, (e.g. Ringer's solution or Hartmann's solution), should not be used to reconstitute ceftriaxone vials or to further dilute a reconstituted vial for IV administration because a precipitate can form. Precipitation of ceftriaxone-calcium can also occur when ceftriaxone is mixed with calcium-containing solutions in the same IV line. Therefore, ceftriaxone and calcium-containing solutions must not be mixed or administered simultaneously.

References:

1. *EMC (Click here)*
2. *Resuscitation Council UK (Click here)*
3. *EMC (Click here)*

The Egyptian Pharmaceutical Vigilance center
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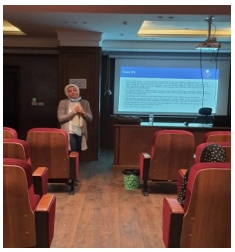
Awareness Sessions in Alexandria and Cairo

Based upon the vision and mission of the Egyptian Pharmaceutical Vigilance Center (EPVC) in spreading the awareness of Pharmacovigilance and the culture of reporting of side effects among Healthcare professionals to promote the safe and effective use of the pharmaceutical products and to promote pharmaceutical care, the Center conducted a training organized by the Institute of Professional Training in the Medical Sector of the Egyptian Ministry of Interior Affairs, attendees were 53 of the pharmacists and nurses, who are affiliated to the Ministry of Interior Affairs hospitals in Alexandria and Cairo governorates.

The training included a lecture and workshop on the basics of Pharmacovigilance, its importance, and how to report adverse events and other safety information related to the different pharmaceutical products such as medicines, vaccines, biological products and medical devices. The attendees showed a great interaction with the lecturers and were convinced by the importance of practicing Pharmacovigilance during their work, for better patient safety.

In a related context, Cairo regional center conduct a training program over four Online sessions directed to 60 pharmacists from the Specialized Medical Centers hospitals (all over Egypt) from 4 to 11 March 2021, Pharmacists showed interaction that reflects their outstanding level.



The program included clarification of the mechanisms of reporting adverse effects in Egypt, stressing the pivotal role of the pharmacist in raising awareness regarding the safety of pharmaceutical and biological preparations and medical devices, establishing a culture of reporting adverse effects among medical staff and patients alike, and monitoring the safe use of the drug.

Renewing the Collaboration with Qaliobya Directorate

In the context of the cooperation plan of the Egyptian Pharmaceutical Vigilance Center; The head of Regional centers & her Deputy, conducted a visit to General Administration of Pharmacy at Qaliobya Directorate where they discussed cooperation and agreed to hold trainings for Pharmacists working at the directorate. Training will start at “Kafr Shokr” Hospital and coordination is underway to hold other trainings

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)

Address: 21 Abd El Aziz AlSoud Street. El-Manial, Cairo, Egypt, PO Box: 11451
Telephone: (+2)02 25354100/ (+2)02 23684288/ (+2)02 23648046/ (+2) 02 23640368/ (+2)02 23648769
Extension: 1303
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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