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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Direct Healthcare Professional Communication (DHPC): Infliximab- Use of Live Vaccines in Infants Exposed in Utero or During Breastfeeding

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

Summary:

Infants exposed to infliximab in utero (i.e., during pregnancy)

* Infliximab crosses the placenta and has been detected in infant serum up to 12 months after birth. After in utero exposure, infants may be at increased risk of infection, including serious disseminated infection that can become fatal.
* Live vaccines (e.g., BCG vaccine) should not be given to infants after in utero exposure to infliximab for 12 months after birth.
* If there is a clear clinical benefit for the individual infant, administration of a live vaccine might be considered at an earlier timepoint if infant infliximab serum levels are undetectable or if infliximab administration was limited to the first trimester of pregnancy.

Infants exposed to infliximab via breast milk

* Infliximab has been detected at low levels in breast milk. It has also been detected in infant serum after exposure to infliximab via breast milk.
* Administration of a live vaccine to a breastfed infant while the mother is receiving infliximab is not recommended unless infant infliximab serum levels are undetectable)

Background:

Infliximab is a chimeric human-murine immunoglobulin G1 (IgG1) monoclonal antibody that specifically binds to human TNFα. In the European Union, it is indicated for the treatment of rheumatoid arthritis, Crohn's disease (adult and pediatric), ulcerative colitis (adult and pediatric), ankylosing spondylitis, psoriatic arthritis, and psoriasis.

Administration of live vaccines to infants exposed to infliximab in utero

Infliximab crosses the placenta and has been detected in the serum of infants exposed to infliximab in utero for up to 12 months after birth (Julsgaard et al, 2016). These infants may be at increased risk of infection, including serious disseminated infection that can become fatal. This includes disseminated Bacillus Calmette Guérin (BCG) infection which has been reported following administration of BCG live vaccine after birth. A 12-month waiting period starting at birth is therefore recommended before live vaccines are administered to infants who have been exposed to infliximab in utero. If there is a clear clinical benefit for the individual infant, administration of a live vaccine might be considered earlier if infant infliximab serum levels are undetectable or if infliximab administration was limited to the first trimester of pregnancy (when placental transfer of IgG is considered minimal).

Administration of live vaccines to infants exposed to infliximab via breast milk

Limited data from published literature indicate that infliximab has been detected at low levels in breast milk at concentrations up to 5% of the maternal serum level (Fritzsche et al, 2012). Infliximab has also been detected in infant serum after exposure to infliximab via breast milk. Systemic exposure in a breastfed infant is expected to be low because infliximab is largely degraded in the gastrointestinal tract. Administration of live vaccines to a breastfed infant when the mother is receiving infliximab is not recommended unless infant infliximab serum levels are undetectable.

References: *EMA (Click here)*

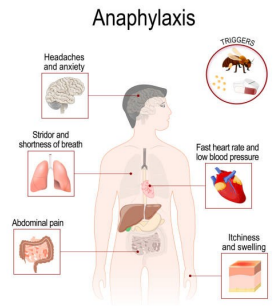
Direct Healthcare Professional Communication (DHPC): Infliximab- Use of Live Vaccines in Infants Exposed in Utero or During Breastfeeding Continued

Live Vaccines Available in Egypt:

1. Bivalent Poliomyelitis Virus
2. Varicella Virus
3. Rotavirus
4. Measles, Mumps and Rubella (MMR) Virus
5. BCG

Case Report from Cairo: Cefotaxime - Anaphylactic shock, Hypersensitivity, Hypoxia and Rash

The regional center in Cairo received a case related to anaphylactic shock, hypersensitivity, hypoxia and rash with the use of Cefotaxime & its details as follows: A female 39 years old weigh 68 Kg received Cefotaxime 1 gm via intramuscular route for general weakness (2 ampoule every day) from 10/03/2022 to 24/03/2022 and then she suffered from high risk allergy, hypoxia and rash through out all her body which required emergency treatment. Then she was prescribed antihistamine tablets and ointment for 2 weeks and patient recovered and drug was stopped. The patient has no history of antibiotics allergies. Concomitant drugs are not mentioned.



Background:

Rash: abnormal changes in skin color or texture. They usually result from skin inflammation, which can have many causes. (1)

Anaphylactic shock: A severe and sometimes life-threatening immune system reaction to an antigen that a person has been previously exposed to. The reaction may include itchy skin, edema, collapsed blood vessels, fainting, difficulty in breathing, and death. (2)

Hypersensitivity: is an immunological dysfunction defined as exaggerated or inappropriate response of the immune system, which is mostly targeted at innocuous antigens with consequent tissue damage. Hypersensitivity can be classified into four types; namely, type I (Immediate), type II (antibody-mediated), type III (immune complex-mediated), and type IV (cell-mediated or delayed-type) hypersensitivity. (3)

Hypoxia: A lower-than-normal concentration of oxygen in arterial blood, as opposed to anoxia, a complete lack of blood oxygen. Hypoxia will occur with any interruption of normal respiration. (4)

Cefotaxime: is a third generation semisynthetic cephalosporin antibiotic with bactericidal activity. Cefotaxime inhibits mucopeptide synthesis by binding to and inactivating penicillin binding proteins thereby interfering with the final transpeptidation step required for cross-linking of peptidoglycan units which are a component of bacterial cell walls. This results in a reduction of cell wall stability and causes cell lysis. (5)

Labeled information:

According to Cefotaxime SPC section "Undesirable effects":
Immune system disorders:
Not known: Anaphylactic reactions and anaphylactic shock.
Skin and subcutaneous disorders:
Uncommon: Rash.

Case Report from Cairo: Cefotaxime - Anaphylactic shock, Hypersensitivity, Hypoxia and Rash Continued

Recommendations for Patients and Healthcare Professionals: [7]

1. Prescribing Cefotaxime in the absence of a proven or strongly suspected bacterial infection or as prophylaxis is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
2. Cefotaxime should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
3. Because high and prolonged serum antibiotic concentrations can occur from usual doses in patients with transient or persistent reduction of urinary output because of renal insufficiency, the total daily dosage should be reduced when Cefotaxime is administered to such patients. Continued dosage should be determined by degree of renal impairment, severity of infection, and susceptibility of the causative organism.
4. Although there is no clinical evidence supporting the necessity of changing the dosage of cefotaxime sodium in patients with even profound renal dysfunction, it is suggested that, until further data are obtained, the dose of cefotaxime sodium be halved in patients with estimated creatinine clearances of less than 20 mL/min/1.73 m^2.
5. As with other antibiotics, prolonged use of Cefotaxime may result in overgrowth of non susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.
6. As with other beta-lactam antibiotics, granulocytopenia and, more rarely, agranulocytosis may develop during treatment with Cefotaxime, particularly if given over long periods. For courses of treatment lasting longer than 10 days, blood counts should therefore be monitored.
7. Cefotaxime, like other parenteral anti-infective drugs, may be locally irritating to tissues. In most cases, perivascular extravasation of Cefotaxime responds to changing of the infusion site. In rare instances, extensive perivascular extravasation of Cefotaxime may result in tissue damage and require surgical treatment. To minimize the potential for tissue inflammation, infusion sites should be monitored regularly and changed when appropriate.

Disclaimer: The method of case handling depends on the evaluation of the treating physician according to individual patient's need.

References:

1. *Webmd (Click here)*
2. *NIH (Click here)*
3. *Science Direct (Click here)*
4. *RxList (Click here)*
5. *NIH (Click here)*
6. *EMC (Click here)*
7. *Rxlist (Click here)*

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Together for Safe Medicine Initiative Progress

We are happy to celebrate the ongoing success of the EDA initiative "together for safe medicine," The initiative was inaugurated in December 2021 and continued till August 2022 including the first and second waves, 189 pharmacies shared in the initiative from both community and hospital pharmacies, The Shared pharmacists made a valuable effort in encouraging the basic concepts of pharmacovigilance and increasing reporting of adverse drug reactions through making 44 different activities Like posters, awareness sessions for HCP in hospitals, patient education about pharmacovigilance importance. In this context, 24 pharmacists were selected as the best participants and top achievers in the first and second waves, and honoring ceremony is anticipated to take place at end of August 2022 where all participants will receive a certificate of honor as appreciation from the pharmacovigilance center - EDA for their efforts in encouraging the basic concepts of pharmacovigilance and the idea of reporting adverse drug reactions for more improvement of patient and drug safety.

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

The Egyptian Pharmaceutical Vigilance Center (EPVC) is delighted to continue the decentralization training in coordination with the Specialized Medical Centers (SMCegy), Chest Hospitals administration and Fayoum directorate hospitals.

The training targeted the pharmacists working in the coordinating institutions to learn how to report using the national database reporting system as an expansion for the pharmacovigilance effort to improve the reporting system and provide an access for the institution on a strong database.

The training was given during July 2022 for each institution over three days online lectures then continued practical training on the National database by Cairo and Alexandria Regional centers.

EPVC Tips On Pharmacovigilance

Why Pharmacovigilance is needed in Every Country?

because of differences in:

- Distribution and use (e.g. indications, dose, availability)
- Production method
- Genetics, diet, traditions of the citizens
- Medical practice
- Pharmaceutical quality and composition of used ingredients

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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)

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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