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

September 2021

Volume 12 **Issue 9**

Colchicine: High risk of fatality with colchicine overdose

Colchicine is indicated for the treatment of acute gout when non-steroidal anti-inflammatory drugs are contraindicated, ineffective or not tolerated. It has a narrow therapeutic index. An overdose of colchicine carries a high risk of fatality and there are no effective treatments available for severe colchicine poisoning.

Review of risk

Colchicine is indicated for the treatment of acute gout when non-steroidal anti-inflammatory drugs are contraindicated, ineffective or not tolerated.

The approved dose for treatment of acute gout is 1 mg (two tablets) at the first sign of the flare, followed by 0.5 mg (one tablet) one hour later. Higher doses have not been found to be more effective. The maximum recommended dose for treatment of acute gout is 1.5 mg (three tablets) over a one hour period. A course of colchicine should not be repeated within three days.

Colchicine has a narrow therapeutic index. The separation between therapeutic and toxic doses is not well defined. Fatal colchicine toxicity has occurred in adults at doses as low as 7 mg when taken for a therapeutic purpose.

The risk of toxicity is increased by co-administration with medicines that inhibit cytochrome P450 3A4 or P-glycoprotein, and comorbidities such as renal or hepatic impairment. Colchicine toxicity is an extension of its mechanism of action. Colchicine inhibits the formation of microtubules, affecting cell division in all cell types of the body, which accounts for both the therapeutic effects and the multi-organ toxicity seen in colchicine poisoning.

There is no antidote for colchicine poisoning. Treatment is usually supportive and involves early administration of activated charcoal.1 Colchicine toxicity has a high mortality rate.

In reference to HPRA; General Advice about Colchicine:

* Gout medicines, like any medicine, can be harmful if not taken correctly.
* Always store your medicines out of sight and reach of children. Store medicines in a locked cupboard or somewhere that your child cannot reach or access
* Never share your medicines with others.
* Stop the medicine and seek urgent medical attention if you experience any of these symptoms:
  - ⇒ nausea
  - ⇒ vomiting
  - ⇒ diarrhoea
  - ⇒ abdominal pain
  - ⇒ blood in the bowel motions
  - ⇒ black tarry bowel motions
  - ⇒ blood in the urine
  - ⇒ rash

References: *HPRA (Click here)*

Fingolimod: Updated advice about the risks of serious liver injury and herpes meningoencephalitis

Fingolimod is authorised to treat patients aged 10 years or older with highly active relapsing-remitting multiple sclerosis that has not responded toat least one disease-modifying therapy or which is severe and rapidly progressive. Liver monitoring requirements and discontinuation criteria for fingolimod have been updated following reports of serious liver injury. Fatal cases of encephalitis and meningitis caused by herpes simplex andvaricella zoster viruses have also been reported during treatment. Advise patients to seek urgent medical attention if they develop any clinical features of liver dysfunction or meningoencephalitis. Discontinue fingolimod if significant hepatic injury or herpes meningoencephalitis is confirmed.

Risk of serious liver injury

In clinical trials, 8% of adult patients receiving fingolimod 0.5mg daily developed increased ALT levelsthat exceeded 3-times the upper limit of normal (ULN) compared with 2% receiving placebo. Fingolimodwas discontinued if serum transaminases were greater than 5-times ULN. Increased transaminaselevels usually occurred within the first year of treatment and returned to normal within 2 months after discontinuation of fingolimod. Re-treatment resulted in increased transaminase levels in some patients, supporting a causal relationship.

A recent European review of safety data identified 7 cases of clinically significant liver injury that developed between 10 days and 5 years after the start of fingolimod treatment, including 3 post-marketing reports of acute hepatic failure requiring liver transplantation. Liver samples showed submassive hepatic necrosis in 2 patients, and one of these samples also contained features of acute hepatitis.

Due to the severity of recently reported cases, recommendations for liver monitoring and the discontinuation criteria have been strengthened to minimize the risks of liver injury

New information on risk of meningoencephalitis

Remind patients to seek immediate medical attention if they have a fever or signs of infection (includinginfluenza or shingles) or if they have symptoms of meningitis or encephalitis during fingolimod treatmentand up to 2 months after the last dose

In reference to MHRA; Advice to give to patients:

* Fingolimod has been associated with a risk of serious liver injury and regular blood tests are needed to identify people at risk of liver damage before, during, and after treatment
* Seek urgent medical attention if you develop any symptoms or signs of liver injury (such as feeling sick or vomiting (without another reason), tiredness, abdominal pain, jaundice (yellow skin or eyes), or dark urine
* Serious and life-threatening cases of a type of brain infection (herpes meningoencephalitis) have been reported
* Seek urgent medical attention if you experience any symptoms of a brain infection during fingolimod treatment and for 8 weeks after the last dose, including seizures (fits), headache, neck stiffness, oversensitivity to light, rash or fever
* Read carefully the patient information leaflet that accompanies your medicine and keep them handy in case you need to read them again.

Fingolimod: Updated advice about the risks of serious liver injury and herpes meningoencephalitis Continued

In reference to MHRA; Advice for Healthcare Professionals:

* A small number of cases of clinically significant liver injury, including acute hepatic failure requiring transplantation, have been reported during fingolimod treatment
* Monitor liver function tests (including bilirubin) routinely: before starting treatment; duringtreatment at months 1, 3, 6, 9 and 12; and then periodically until 2 months after discontinuation
* In patients without signs and symptoms of liver injury, the updated advice is:
  - ⇒ monitor liver function tests more frequently if serum aspartate aminotransferase (AST) or serum alanine aminotransferase (ALT) levels exceed 3-times the upper limit of normal (ULN) but less than 5-times ULN with a normal bilirubin level
  - ⇒ discontinue fingolimod if ALT or AST levels exceed 5-times ULN or if they are at least 3-times the ULN and bilirubin is increased – fingolimod may be re-started following a careful benefit-risk assessment of the underlying cause when serum levels have returned to normal
* In patients with symptoms or signs of hepatic dysfunction:
  - ⇒ check liver function tests urgently
  - ⇒ discontinue fingolimod if significant hepatic injury is confirmed; further treatment with fingolimod may be considered following recovery only if an alternative cause of hepatic dysfunction is established
* continue to be vigilant for infections with fingolimod; information has been updated to include herpes zoster/herpes simplex infections with visceral or CNS dissemination

References:

MHRA (Click here)

Pharmacovigilance Awareness Sessions in East Medical District

In the context of the vision and mission of the Egyptian Pharmaceutical Vigilance Center (EPVC) in spreading the awareness of the pharmacovigilance and the culture of reporting of side effects among the Healthcare professionals to promote the safe and effective use of the different pharmaceutical products and to promote the pharmaceutical care, the center conducted a training on pharmacovigilance organized by East medical district, attendees were 10 of the pharmacists from different healthcare units.

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, biologicals and medical devices.

The Egyptian Pharmaceutical Vigilance center
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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
مركـــز اليـــقظة الصـــيدلية المـــصري

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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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