هيئة الدواء المصرية

IN THIS ISSUE

Prepared by:

Reem Tarek
Doaa Marzouk
Aya Nabil
Mariam Morkos
Maysa Hussein
Asmaa Shalaby

Designed by:

Reem Tarek

Chief Editor

Walaa Ebrahim

Head of Egyptian Pharmaceutical vigilance centre

Under Supervision of

Dr. Sherin Abdel Gawad

Head of the C.A for Pharmaceutical Care Center

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

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

May 2024

Volume 15 Issue 5

Safety Notification ! : Unintentional poisoning of some products

The Regulatory Authority in New Zealand has published the following safety notification:

Key messages

- Some medicines can be highly toxic to people or pets, even in small amounts.
- Young children are at particular risk of unintentional poisoning from medicines.
- Consider safe prescribing strategies when prescribing medicines that are known to be harmful when used inappropriately.
- Remind patients to: keep all medicines out of sight and reach of children and pets never share prescription medicines.

Substances found around the house, including medicines, are common causes of unintentional poisoning in children and pets. About 20 percent of families with preschool age children experience a poisoning every year. However, it is important to remember that people of any age can be poisoned by medicines found in the home.

General considerations

The risks associated with a poisoning will depend on several factors relating to the medicine (eg, the type and quantity of the medicine involved, the route of exposure) and individual characteristics such as age, weight, medical history. While most exposures are unlikely to have serious outcomes, some medicines can cause serious toxicity or death, even in very small amounts.

Poisoning in children

More than half of calls to the New Zealand National Poisons Centre relate to children aged under 5 years, and children aged 1 to 3 years are the most likely age group to be poisoned. This includes poisoning from household chemicals and medicines.

Examples of medicines most commonly reported in poisonings of children aged under 5 years

Paracetamol / Anti-inflammatories / Thyroid medicines / Multivitamins / Antihistamines / Antibiotics / Oral contraceptives / Cold and flu medicines

Examples of medicines that can cause significant toxicity in children in small amounts

Class	Examples
Calcium channel blockers	Diltiazem, verapamil
Opioids	Morphine, fentanyl
Tricyclic antidepressants	Amitriptyline, nortriptyline
Sulfonylureas	Glipizide, gliclazide
Anti-gout medicines	Colchicine

Safety advice

Consider safe prescribing strategies when prescribing medicines that are known to be harmful when used inappropriately Remind patients to:

- Keep all medicines out of sight and reach of children and pets
- Never share prescription medicines
- Store medicines in their original containers and separately from food
- Put medicines away immediately after use
- Not rely on child-resistant caps (they are not child-proof)
- Safely dispose of old or unused medicines by returning them to the pharmacy.

In addition, remind patients using topical medicines to: avoid letting pets contact or lick the container or the skin where the medicine was applied

- Wash hands thoroughly after using
- Safely discard or clean any items (eg, cloths, applicators, clothing) that may contain medicine residue.

References:

MedSafe : *(Click Here)*

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

Safety Notification ! : Furosemide exposure during pregnancy

The regional center in Cairo recently received a case involving a 27-year-old pregnant woman in her second trimester. Her medical history is unknown, but she has previously taken medications such as Ivabradine, Cefipime, Nor epinephrine, and Clarithromycin. She was administered Furosemide intravenously at a rate of 4cm/hour for 5 days to manage pulmonary edema.

In this newsletter topic, we'd like to emphasize the precautions to be taken before using Furosemide during pregnancy. Close monitoring of fetal growth is essential as Furosemide falls under FDA category C and crosses the placenta.

Background (1,2):

Furosemide : Furosemide is a loop diuretic used to treat fluid retention (edema) in people with congestive heart failure, liver disease, or a kidney disorder such as nephrotic syndrome. Furosemide is also used to treat high blood pressure (hypertension).

Usual Adult Dose for Pulmonary Edema:

IV: 40 mg IV slowly over 1 to 2 minutes; if a satisfactory response doesn't occur within one hour, may increase to 80 mg IV slowly over 1 to 2 minutes.

Pulmonary edema: Pulmonary edema is a condition caused by too much fluid in the lungs. This fluid collects in the many air sacs in the lungs, making it difficult to breathe.

Labeled information of Furosemide Solution for injection (3):

According to Furosemide 40 mg/4ml Solution for injection SPC:

-Furosemide crosses the placental barrier and should not be given during pregnancy

unless there are compelling medical reasons. It should only be used for the pathological causes

of oedema which are not directly or indirectly linked to the pregnancy.

The treatment with diuretics of oedema and hypertension caused by pregnancy is undesirable because placental perfusion can be reduced, so, if used, monitoring of fetal growth is required.

However, furosemide has been given after the first trimester of pregnancy for oedema, hypertension

and toxaemia of pregnancy without causing fetal or newborn adverse effects.

Furosemide Pregnancy Warnings (4,5)

Animal studies have revealed evidence of fetolethality. There are no controlled data in human pregnancy. The effects of furosemide on embryonic and fetal development and on pregnant dams were studied in mice, rats and rabbits. Furosemide caused unexplained maternal deaths and abortions in the rabbit at the lowest dose of 25 mg/kg (approximately 4 times a human IV dose of 80 mg based on BSA and oral bioavailability corrections).

AU TGA pregnancy category C: Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.

US FDA pregnancy category C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Safety Notification ! : Furosemide exposure during pregnancy (Continued)

This drug should not be used during pregnancy unless the benefit outweighs the risk to the fetus; use is contraindicated according to some authorities.
Comments: Use of this drug during pregnancy requires monitoring of electrolytes, hematocrit, and fetal growth.

Information for healthcare professionals (6):

Furosemide was a pregnancy category C drug under the old FDA categories.
Furosemide is known to cross the placenta, and animal reproduction studies have shown adverse events.
Clinicians should use caution in pregnant women after discussion with the patient about risks and benefits.
Caution is necessary with the decision to take furosemide during pregnancy; fetal growth will require close monitoring.

References:

1) what is furosemide (Click Here)
2) What is Pulmonary edema :(Click Here)
3) Furosemide SPC": (Click Here)
4) Furosemide Pregnancy Warning : (Click Here)
5) Furosemide Pregnancy Warning (Click Here)
6) Information for healthcare professionals ": (Click Here)

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

The Egyptian Pharmaceutical Vigilance Center (EPVC) is excited to extend VigiFlow Expansion training to new organizations and to provide advanced training to the institutions that exhibited mature performance, in collaboration with various healthcare partners. Beyond emphasizing the importance of the reports data completeness, this training seeks to enhance data entry in the national database reporting system and extends gratitude to the focal points of these organizations.

To maintain the highest standard of quality for cases in the national database, EPVC conducts training sessions to receive, review, and provide valuable feedback on cases. This collaborative effort ensures continuous improvement and identifies areas where additional training may be beneficial. Hence, better safety monitoring.

EPVC extends heartfelt thanks to all organizations that have partnered in the VigiFlow Expansion project. Their commitment to submitting cases to the national database is commendable, and EPVC looks forward to their continued success in advancing case quality and quantity.

We are going to assess the cases that have been received and offer feedback to the coordinating organizations in an attempt to raise the caliber of the cases that have been entered into the national database.

Tanta University hospitals first Pharmacovigilance fair EPVC participation:

The Egyptian Pharmaceutical Vigilance Center (EPVC) is thrilled to join the first Pharmacovigilance fair at Tanta University hospitals. Our contribution included an advanced level session for healthcare professionals which aimed to underline the importance of achieving the highest standard of quality for Individual Case Safety Reports submitted to the national database.

"Together for Safe Medicine" Initiative News:

We are Extremely proud of the Success for 4th wave of EPVC initiative "Together for safe medicine". As it was started on 22 February 2024 with the sharing of 87 Pharmacists from 83 Pharmacies were divided into 41 community pharmacies and 42 hospital pharmacies shared from 23 different governates all over Egypt. Where the participants sent **641** Adverse drug reaction reports on our national database vigiflow from the start of the initiative till 1 May 2024 and they are continuing to send more ADR reports with improving the quality of the sent reports. where 641 reports were divided into 271 reports received through E-reporting Link and 370 reports received through official vigiflow accounts for our participants in governmental hospitals. The participants had applied a lot of activities for spreading and applying pharmacovigilance science in community, private and governmental pharmacies all over Egypt governorates and not only through their workplaces but also through social media such as Facebook, Linkedin, TV programs, and YouTube channels which made a widespread for Pharmacovigilance science to different Egyptian citizens it was there first time to know about pharmacovigilance.

The Egyptian Pharmaceutical Vigilance center
مركز اليقظة الصيدلية المصري

EPVC Tips

On Pharmacovigilance

Precautions for using medicines during pregnancy and breastfeeding

The treatment of common medical conditions during pregnancy frequently becomes complicated due to the potential effects that medications can have on fetal growth and development.

While the use of many medications during pregnancy has drastically declined in recent years as new information about their risks surfaces, the use of others has increased as recent research has reassured their safety.

Information regarding the risks of medication use during pregnancy and lactation remains relatively limited due to barriers to clinical research.

The role of the health care professional team is making appropriate medication selection.

Visit EDA website to find all 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

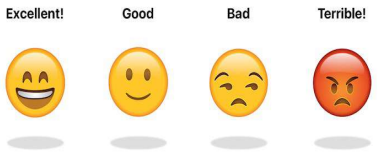
One report counts

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

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

هيئة الدواء المصرية (الرعاية الصيدلية)