EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

EPVC

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

July 2022

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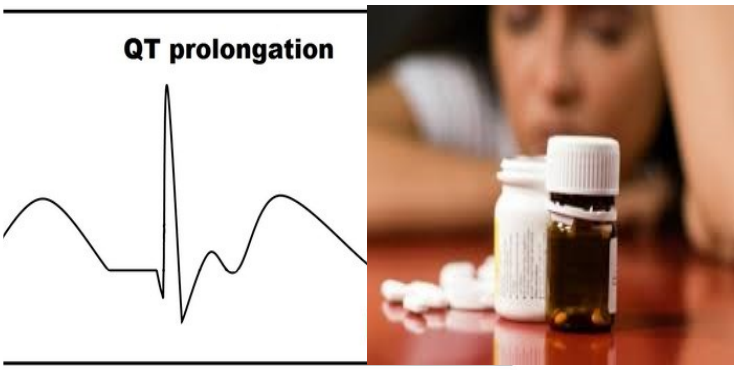
Direct Healthcare Professional Communication (DHPC): Citalopram and Escitalopram - Risk of Dose-dependent QT interval Prolongation

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

Summary:

* The dose-dependent risk of prolongation of the QT interval maximum dosages are as follows:
  - Citalopram: 40 mg per day in adults, and 20 mg per day in patients aged over 65 and/or with hepatic impairment
  - Escitalopram: 20 mg per day in adults and 10 mg per day in patients aged over 65 and/or with hepatic impairment
* Contraindications
  - In combination with other medicinal products known to induce prolongation of QT interval including:
    - ⇒ class IA and III antiarrhythmics
    - ⇒ antipsychotics and tricyclic antidepressants
    - ⇒ certain anti-microbial agents (example: sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatments in particular halofantrine),
    - ⇒ certain antihistamines (astemizole, hydroxyzine, mizolastine)
  - In patients with acquired or congenital prolongation of the QT interval
* They should be used with caution in patients at risk, especially those with:
  - significant bradycardia
  - recent acute myocardial infarction
  - unstable heart failure



* It is necessary to correct electrolyte abnormalities before starting treatment (hypokalaemia or hypomagnesemia which increase the risk of arrhythmia)

Background:

From 2011, the SPCs for Citalopram and Escitalopram were amended to include the risk of dose-dependent prolongation of the QT interval, and consequently a reduction in the maximum authorized doses, in particular in elderly subject, as well as new contraindications and precautions for use.

In 2019, the study conducted in France by Chastang et al. assessed the prevalence and impact of interventions by pharmacists following the combination of citalopram or escitalopram with other medicinal products known to induce prolongation of the QT interval. This study concludes that a high number of hospital prescriptions for citalopram or escitalopram presents a contraindicated combination with other drugs known to induce prolongation of the QT interval. The classes of drugs most frequently found were: antiarrhythmics (amiodarone, sotalol), antipsychotics (haloperidol, cyamemazine, amisulpride, chlorpromazine, tiapride) and antiemetics (droperidol) which can cause Torsades de Pointes if combined with citalopram or 'escitalopram.

References: *ANSM (Click here)*

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Case Report from Sohag: Isotretinoin - Case of Skin rash, Skin dryness & Blurred vision

The regional center in Sohag received 1 case related to Skin rash, Dry skin & Blurry vission with the use of Isotretinoin. Male adult 20 years old received Isotretinoin 40 mg Soft Gelatin Capsule with the dose of 40 mg once per day as a treatment for Acne orally from 11/04/2022 to 18/04/2022 (8 days). The patient suffered from skin rash, skin dryness and blurry vision from 11/04/2022 which resolved after drug withdrawal.

Background:

Skin rash: Abnormal changes in skin color or texture. They usually result from skin inflammation, which can have many causes[1] .

Skin dryness: When your skin dries out because it doesn't have enough moisture. It isn't usually serious, but it can be irritating. There are many causes of dry skin - from the temperature outside to how much moisture is in the air - and many types[2] .

Blurred vision: Blurred vision is when you cannot see fine details. You may have blurred vision if you are nearsighted or farsighted and you need glasses. Blurred vision may be caused by a corneal abrasion (scratch on the cornea) or a corneal ulcer (open sore). Medical conditions, such as cataracts, glaucoma, detached retina, and nerve disorders can also cause blurred vision[3] .

Isotretinoin: Isotretinoin is a form of vitamin A that is used to treat severe nodular acne that has not responded to other treatments, including antibiotics[4] .

Labeled information:

According to (**Isotretinoin**) article it was stated under section "**Isotretinoin side effects**": [4]

- Get emergency medical help if you have signs of an allergic reaction (hives, difficult breathing, swelling in your face or throat) or a severe skin reaction (fever, sore throat, burning eyes, skin pain, red or purple skin rash with blistering and peeling).
- Isotretinoin may cause serious side effects. Stop using isotretinoin and call your doctor at once if you have: problems with your vision or hearing; vision problems, pain behind your eyes.
- Common side effects of isotretinoin may include: dryness of your skin, lips, eyes, or nose (you may have nosebleeds); vision problems; skin reactions.[6]
- A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash

According to **Isotretinoin Capsule—Uses, Side effects, and more** article; it was stated under section

Case Report from Sohag: Isotretinoin - Case of Skin rash, Skin dryness & Blurred vision Continued

"**Side Effects**": [5]

- Dry lips and mouth, minor swelling of the eyelids or lips, crusty skin, nosebleeds
- Stop taking this medication and tell your doctor right away if you have any very serious side effects, including: vision changes

According to **(Isotretinoin)** article it was stated under section "**Adverse Effects**": [6]

- Cheilitis or dry lips are the most common dose dependent adverse effect seen in about 90% of patients taking isotretinoin. Dry skin (xerosis), dry mouth (xerostomia), dry nose, and sun sensitivity are also very common adverse effects seen in patients taking isotretinoin
- **Other Potential Adverse Effects:** Itching (pruritis), irritation, hair thinning, skin fragility, dry eyes, skin infections, rash.

According to **(Isotretinoin)** Summary of product Characteristics (SmPC) section "**ADVERSE REACTIONS**": [7]

- **Clinical Trials and** Postmarketing **Surveillance:** The adverse reactions listed below reflect the experience from investigational studies of Isotretinoin, and the postmarketing experience. The relationship of some of these events to Isotretinoin therapy is unknown. Many of the side effects and adverse reactions seen in patients receiving Isotretinoin are similar to those described in patients taking very high doses of vitamin A (dryness of the skin and mucous membranes, eg, of the lips, nasal passage, and eyes).
- Stop taking this medication and tell your doctor right away if you have any very serious side effects, including: vision changes"
- **Vision:** corneal opacities, decreased night vision which may persist, cataracts, color vision disorder, conjunctivitis, dry eyes, eyelid inflammation, keratitis, optic neuritis, photophobia, visual disturbances.

According to **(Isotretinoin)** it was stated under section "**For Healthcare Professionals**": [8]

- **General:** The most commonly reported side effects include dryness of the skin and mucous membranes (e.g., cheilitis, epistaxis, conjunctivitis)" "**Dermatologic:** In some cases, acne flares occurred during the initial stages of treatment and persisted for several weeks. Common (1% to 10%): Dermatitis, dry skin, localized exfoliation, pruritus, rash erythematous, skin fragility/risk of frictional trauma.
- **Ocular:** Common (1% to 10%): Conjunctivitis, dry eye, eye irritation. Very rare (less than 0.01%): Blurred vision.

Case Report from Sohag: Isotretinoin - Case of Skin rash, Skin dryness & Blurred vision Continued

Recommendations for Patients and Healthcare Professionals

1. Isotretinoin in just a single dose can cause severe birth defects or death of a baby. Never use isotretinoin if you are pregnant or able to become pregnant (Embryo-Fetal Toxicity).[4]
2. You must have a negative pregnancy test before taking isotretinoin. You will also be required to use two forms of birth control to prevent pregnancy while taking this medicine. [4]
3. Always take isotretinoin with a full glass of water. Do not chew or suck on the capsule. Swallow it whole.[4]
4. Use isotretinoin for the full prescribed length of time. Your acne may seem to get worse at first, but should then begin to improve.[4]
5. You may need frequent blood tests.[4]
6. In case of missed dose; skip the missed dose and use your next dose at the regular time. Do not use two doses at one time.[4]
7. Do not take a vitamins or minerals supplement that contains vitamin A while using isotretinoin.[4]
8. Do not donate blood while taking isotretinoin and for at least 30 days after you stop taking it. Donated blood that is later given to a pregnant woman could lead to birth defects in her baby if the blood contains any level of isotretinoin. [4] [6]
9. Avoid driving or hazardous activity until you know how isotretinoin will affect you. Isotretinoin may impair your vision, especially at night.[4]
10. Patients should take some formulations of this drug with food to decrease the risk of esophageal irritation.[4] [7]
11. Usual Adult Dose for Acne: Maintenance dose: 0.25 to 0.5 mg/kg orally 2 times a day. The safety and efficacy of once-a-day dosing has not been established; thus, once a day dosing is not recommended.[4]
12. Stop taking this medication and tell your doctor right away if you have any very serious side effects, including: vision changes.[5]
13. Before taking isotretinoin, tell your doctor or pharmacist if you are allergic to it; or to vitamin A-related drugs (other retinoids such as tretinoin); or if you have any other allergies. This product may contain in-

Case Report from Sohag: Isotretinoin - Case of Skin rash, Skin dryness & Blurred vision Continued

active ingredients (such as soybean, parabens), which can cause allergic reactions or other problems. Some people who are allergic to peanuts may also be allergic to soy.[5]

14. This medication may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps (sunlight or tanning beds). Use sunscreen (SPF 30 or higher) and wear protective clothing when outdoors. Tell your doctor right away if you get sunburned or have skin blisters/redness.
15. If you wear contact lenses, you may not tolerate them as well as usual while using this medication.[5][7]
16. Since this drug can be absorbed through the skin and lungs and may harm an unborn baby, women who are pregnant or who may become pregnant should not come in contact with this medication .[5]
17. It is unknown if this medication passes into breast milk. However, similar drugs pass into breast milk. Breast-feeding while using this drug is not recommended.[5]
18. It is important to educate patients about sun protection, skin moisturizers and barriers before starting the medication. Patients should also avoid all skin resurfacing procedures (waxing, dermabrasion, laser therapy) during treatment and at least six months after treatment to prevent skin irritation and scarring.[6]
19. Visual problems should be carefully monitored. All Isotretinoin patients experiencing visual difficulties should discontinue treatment and have an ophthalmological examination.[7]
20. Patients may be at increased risk when participating in sports with repetitive impact where the risks of spondylolisthesis with and without pars fractures and hip growth plate injuries in early and late adolescence are known. There are spontaneous reports of fractures and/or delayed healing in patients while on therapy with Isotretinoin or following cessation of therapy with it while involved in these activities.[7]

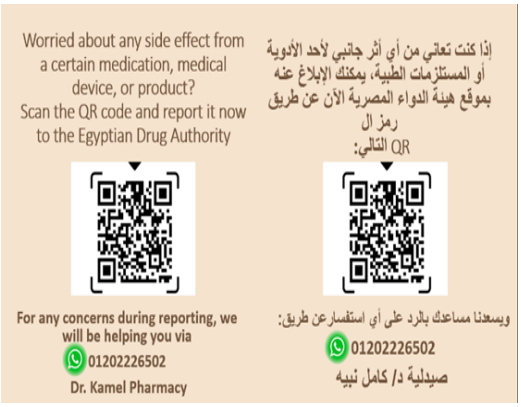
Disclaimer: The method of case handling depends on the evaluation of the treating physician according to individual patient's need.

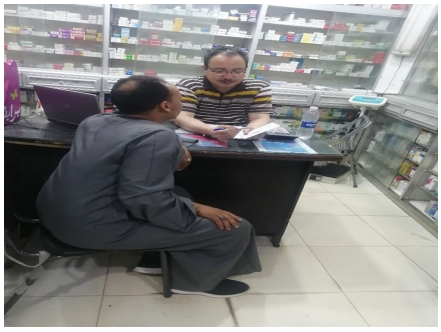
References:

1. *Webmd(Click here)*
2. *Webmd(Click here)*
3. *Drugs.com (Click here)*
4. *Drugs.com (Click here)*
5. *Webmd(Click here)*
6. *NIH (Click here)*
7. *FDA (Click here)*
8. *Drugs.com (Click here)*

Together for Safe Medicine Initiative Progress

We are happy to celebrate the ongoing success of the Executive phase of the second wave of the EDA initiative "together for safe medicine," which aims to enhance the health care services introduced to Egyptian citizens in both the community and hospitals pharmacies. In this context, an event has been planned where pharmacists who participated in the first and second waves will receive certificates as a token of appreciation from the pharmacovigilance center - EDA for their efforts. These pharmacists were effective in encouraging the basic concepts of pharmacovigilance and the idea of reporting adverse drug reactions to the general public. The event is anticipated to take place in August 2022.





Dr. Mahmoud Thabet Pharmacy
Sohag Governorate

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

The Egyptian Pharmaceutical Vigilance Center (EPVC) is delighted to launch a decentralization training in coordination with the Specialized Medical Centers (SMCegy), University Hospitals, Chest Hospitals administration and some private Hospitals as: Dar Al Foaad Hospital and Celopatra hospitals.

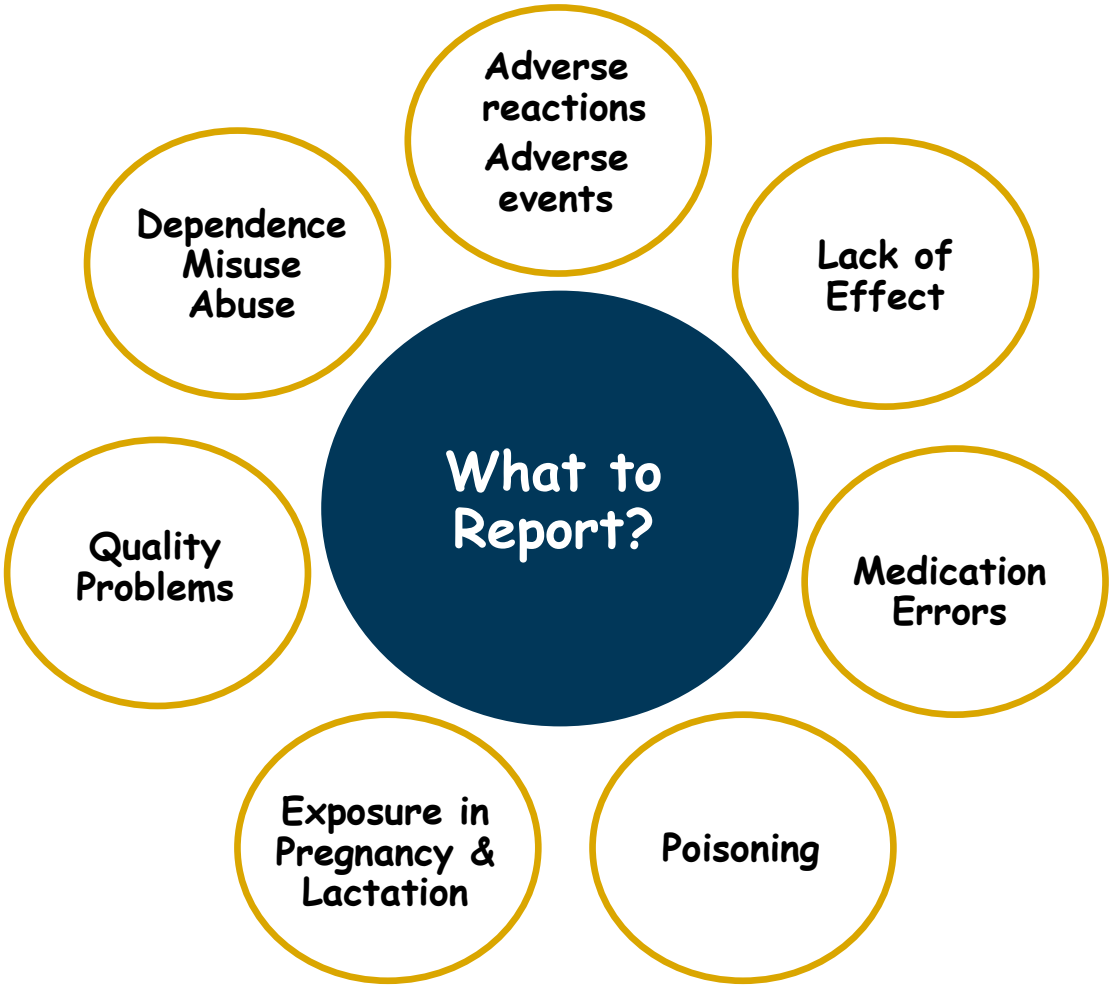
The Training targeting the pharmacists working in the coordinating institutions to learn how to report using the national database reporting system as an expansion for the pharmacovigilance effort to improve the reporting system and provide an access for the institution to a strong database.

The Training started in May 2022 then continued in June 2022 by Cairo and Alexandria Regional Center of pharmacovigilance.

The Training extended for three days online lectures then continued by two days practical training on the National database in both Cairo and Alex. Regional centers.

EPVC Tips On Pharmacovigilance

Spontaneous Reporting is the Backbone of Pharmacovigilance



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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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