



هيئة الدواء المصرية

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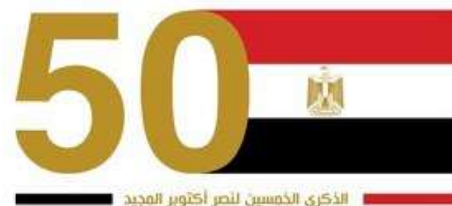
## EPVC Mission

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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## Safety Alert ! : Fluoroquinolone antibiotics: suicidal thoughts and behavior

Healthcare professionals prescribing fluoroquinolone antibiotics (ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, ofloxacin) are reminded to be alert to the risk of psychiatric reactions, including depression and psychotic reactions, which may potentially lead to thoughts of suicide or suicide attempts. Healthcare professionals are also reminded to advise patients to

be alert to these risks.

### **Advice for healthcare professionals:**

- Advise patients to carefully read the advice in the Patient Information Leaflet about possible psychiatric reactions, and to seek medical advice if they experience these symptoms
- When prescribing a fluoroquinolone, advise patients to be alert to any mood changes, distressing thoughts, or feelings about suicide or harming themselves at any point during treatment
- Note that fluoroquinolones can exacerbate existing psychiatric symptoms
- Advise patients to seek medical advice if they develop such thoughts or behaviors, and ensure that a suitable referral for treatment is made, if necessary
- Fluoroquinolones should be discontinued at the first signs of a serious adverse reaction, including new or worsening depression or psychosis
- Report suspected adverse drug reactions (ADRs) to the Yellow Card scheme

### **Advice for healthcare professionals to provide to patients and caregivers:**

- Fluoroquinolone antibiotics are a group of antibiotics that include ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin – sometimes these medicines may also have a brand name so patients should check the details of all antibiotics prescribed to them
- If you are prescribed one of the antibiotics listed above and you suffer from depression or psychosis, tell your healthcare professional – this is important as your symp-



SUICIDAL FEELING

toms may become worse under treatment

- Psychiatric reactions include confusion, disorientation, anxiety, depression and suicidal thoughts or suicide attempts
- You may not notice some changes in your mood and behavior so it is very important to tell your friends and family that you are taking these medicines, and that they have rare psychiatric side effects associated with them – others may notice changes and help you quickly identify any symptoms that you need to talk to your doctor about
- If you develop thoughts of suicide or have attempted suicide, do not take any further doses of your fluoroquinolone, and talk to your doctor or another healthcare professional immediately

### **References:**

**MHRA:** [\(Click Here\)](#)





## Local Case Report

### Case report from Cairo: Four cases of serious extrapyramidal side effects after wrong drug dispensing and dose administration of Cyclizine intravenous injection

The regional center in Cairo received 4 cases suffering from extrapyramidal side effects after the administration of Cyclizine 50 mg/ml intravenous injection.

Four infants with ages (7 months, 1 year, 8 months, 8 months) and average body weight ranges from 5 to 8 Kgs started to administer Cyclizine injection with the doses of 0.9 cm (equivalent to 45 mg), 0.5 cm (equivalent to 25 mg), 0.7 cm (equivalent to 35 mg) and 0.5 cm (equivalent to 25 mg) respectively by intravenous route .

The drug was wrongly dispensed and the dose was calculated based on that of Ondansetron (2mg/ml), in which Cyclizine was not licensed for use in children and a high wrong dose was administered.

After the first dose, the infants suffered from Extrapyramidal symptoms including shivering and abnormal movements.

The drug was withdrawn and not administered again and the four infants recovered spontaneously.

#### **Background:**

Cyclizine: first generation antihistamines and antiemetics that belongs to the piperazine class. Cyclizine is most commonly used to treat the symptoms of nausea, vomiting and dizziness associated with motion sickness. However, it is also used to review symptoms of allergic rhinitis and the common cold, particularly in combination with sympathomimetic agents such as phenylephrine. Cyclizine was first approved for use in the United States in 1966 [1].



Extrapyramidal side effects: are commonly referred to as drug-induced movement disorders are among the most common adverse drug effects patients experience from dopamine-receptor blocking agents. A variety of movement phenotypes has since been described along the EPS spectrum, including dystonia, akathisia, and parkinsonism, which occur more acutely, as well as more chronic manifestations of tardive akathisia and tardive dyskinesia [2].

The Pharmacovigilance Committee (PVC) based on the Egyptian Pharmaceutical Vigilance Center (EPVC) assessment decided that: “After EPVC assessment & study; PVC decides, restriction of Cyclizine use in children under six years of age and address pharmacological committee to obligate marketing authorization holders of products containing Cyclizine, to update product label so as to include restriction of use in children under six years”





## Local Case Report

### Case report from Cairo: Four cases of serious extrapyramidal side effects after wrong drug dispensing and dose administration of Cyclizine intravenous injection (Continued)

#### Labeled information:

According to Cyclizine Lactate 50 mg/ml Injection Summary of product Characteristics (SmPC) it was stated under Warnings and precautions that injection is not recommended for use in children and regarding to the method of administration For Adults 50 mg intramuscularly or intravenously up to three times daily with slow intravenous injection 20 minutes before the anticipated end of surgery. For child 6-11 years 25 mg up to 3 times daily and Child 12-17 years 50 mg up to 3 times daily. While for Paediatric population: Not licensed for use in children. For the undesirable effect in Nervous system Effects on the central nervous system have been reported with cyclizine these include somnolence, drowsiness, incoordination headache, dystonia, dyskinesia, extrapyramidal motor disturbances, tremor, convulsions, dizziness, decreased consciousness, transient speech disorders, paraesthesia and generalised chorea [3].

Based on the SPC of Ondansetron recommended dose for pediatric patients 6 months through 18 years of age, the intravenous dosage is three 0.15-mg/kg doses up to a maximum of 16 mg per dose Thus the drug was wrongly dispensed and the dose was calculated based on the dose of Ondansetron which considered a high dose of Cyclizine injection.

#### Recommendations for Healthcare professionals:

Based on what was stated in the report, the following was recommended:

- Get sure of the exact trade name of the dispensed drug.
- Cyclizine wasn't recommended for use in Paediatric population.

- Educational materials and awareness sessions have to be held for the exact use and dose of Cyclizine injections.



#### Movements of the Mouth

Such as frowning, sticking out tongue, lip smacking, puckering, and pursing



#### Rapid Movements of the Body

Commonly in the arms, legs, and trunk



#### Face

Disfigured facial features such as drooping of the mouth or eyes



#### Eyes

Rapid blinking

#### References:

**[1] Cyclizine background:** [\(Click Here\)](#)

**[2] Extrapyramidal side effects background** [\(Click Here\)](#)

**[3] Cyclizine injection SPC:** [\(Click Here\)](#)



## EPVC News

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

The Egyptian Pharmaceutical Vigilance Center (EPVC) is pleased to confirm the ongoing continuation of the Vigiflow Expansion program. EPVC remains actively engaged in receiving and reviewing cases through the national database. We are committed to providing constructive feedback to coordinating organizations, illustrating our dedication to the continuous enhancement of pharmacovigilance practices. This proactive strategy is expected to result in a more resilient and reliable method for monitoring and managing pharmaceutical safety issues.

EPVC would also like to express sincere gratitude to all coordinating organizations for their diligent efforts and extend our best wishes for their future endeavors.

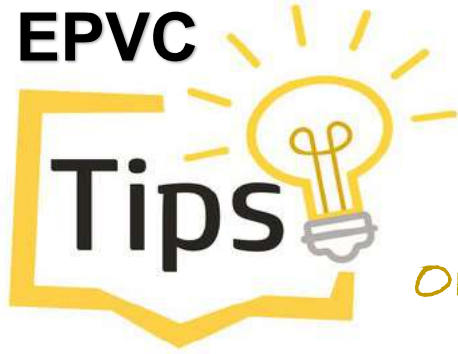
### Egyptian Pharmaceutical Vigilance Center (EPVC) Vigiflow Awareness Campaign

In line with the Egyptian Pharmaceutical Vigilance Center's commitment to raising awareness about the importance of pharmaceutical vigilance and fostering a culture of reporting adverse effects among healthcare professionals, the center conducted a pharmacovigilance training lecture in collaboration with the East Medical District. Twenty-eight pharmacists from diverse healthcare units attended. The lecture covered the fundamental principles of pharmacovigilance, its importance, and the procedures for reporting adverse events and other safety-related information related to a wide range of pharmaceutical products, including medications, vaccines, biologics, and medical devices.

Furthermore, the Alexandria Health Directorate arranged a separate lecture aimed at acquainting attendees with the Egyptian Pharmaceutical Vigilance Center and the different channels available for reporting adverse effects. This lecture was attended by 26 pharmacists representing different hospitals and healthcare units under the jurisdiction of the directorate.



EPVC



On Pharmacovigilance



## Questions to ask before taking a medicine:

As a health care professional you have to give the patient to ask about the medicines you are prescribed..

It helps him to know what to expect if he take a medicine, stop taking it or don't take it at all.

e.g.: What are the likely benefits of taking this medicine?, What side effects should he be aware of?, What would happen if he didn't take this medicine?, How will he know if the medicine is working and how long will that take?, What other treatment options are available?, How does he take the medicine and for how long? and How much will it cost?.



Visit **EDA** website to find all any 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](#)



## One report counts

### 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

### A call for reporting

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

Hotline: 15301

Fax: +202 – 23610497

Email: [pv.followup@edaegypt.gov.eg](mailto:pv.followup@edaegypt.gov.eg)

Reporting link: [www.edaegypt.gov.eg](http://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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