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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 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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Label Update : Drug-induced aseptic meningitis

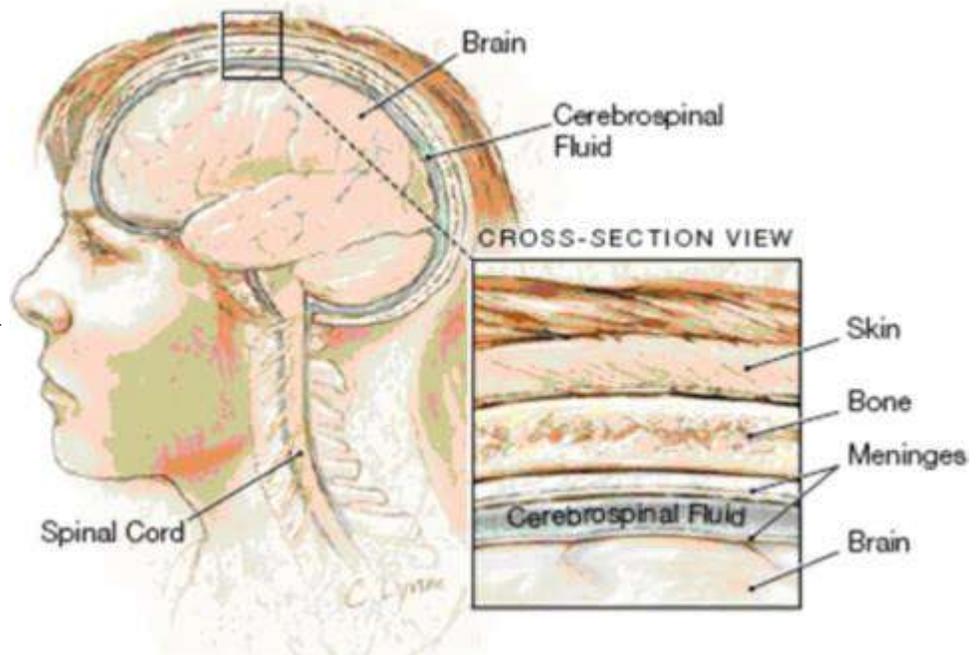
- The regulatory authority in Switzerland published the following label update whose key message is: Medicinal products can be overlooked as triggers of aseptic meningitis. Meningitis may be attributable to both infectious and non-infectious (what is called aseptic meningitis) causes. In addition to systemic diseases with a meningeal component, such as Behçet's disease or sarcoidosis (neurosarcoidosis), or cancer, the causes of aseptic meningitis may include medicines. The medicinal products that have been associated with meningitis include non-steroidal anti-inflammatories (NSAIDs), antibiotics (sulfonamides, penicillins), intravenous immunoglobulin and monoclonal antibodies.

Summary and Recommendation

Aseptic meningitis can be a rare or very rare side effect of certain medicines as e.g. ibuprofen, mefenamic acid or co-trimoxazole. Patients with autoimmune diseases such as lupus erythematosus are predisposed to it after taking NSAIDs. However, the side effect can also occur in healthy people.

The pathophysiology has not been explained definitively. Immunological hypersensitivity reactions (type III/IV) are being discussed, as is direct chemical irritation of the meninges for co-trimoxazole and IVIg. In the case of IVIg, an IgG antigen interaction at the meningeal vessels could be causing cytokine secretion. The symptoms generally begin within hours or days of initial exposure, or often within a matter of minutes to a few hours after renewed exposure. They normally subside quickly and without any complications after the medicine has been discontinued. Aseptic meningitis should be considered in the differential diagnosis when patients present with typical symptoms in conjunction with suspicious medicines.

In Egypt, this risk is addressed in all products containing the same API



References

1. Swiss medic: [\(click here\)](#)

References

Local Case Safety Report: A parent child report of excessive sleep Following maternal administration of Escitalopram

Reason for publishing

The Regional Pharmacovigilance Center in Cairo received an Individual Case Safety Report (ICSR) concerning a parent-child case involving a 33-year-old female patient. She had initiated treatment with Escitalopram 10 mg, taken as one tablet once daily at bedtime, for the management of depression.

Four days after starting the medication, she observed that her infant developed excessive sleepiness. The mother continued the treatment without interruption, and the reported reaction has not yet resolved.

Background:

Depression: is a common mental disorder. It involves a depressed mood or loss of pleasure or interest in activities for long periods of time.

Symptoms:

- Poor concentration
- Feelings of excessive guilt or low self-worth
- Hopelessness about the future
- Thoughts about dying or suicide
- Disrupted sleep
- Changes in appetite or weight
- Feeling very tired or low in energy

Escitalopram:

is a selective serotonin re-uptake inhibitor used in the treatment of major depressive disorder (MDD), generalized anxiety disorder (GAD), and other select psychiatric disorders such as obsessive-compulsive disorder (OCD).

Mechanism of action:

SSRIs exert their mechanism of action by binding to the sodium-dependent serotonin transporter protein (SERT) in the presynaptic neuron. SERT is responsible for reuptaking serotonin from the synaptic cleft into the presynaptic neuron. Inactivation of SERT by escitalopram leads to an elevation in synaptic serotonin levels.[7]

Serotonin, also known as 5-hydroxytryptamine (5-HT), is a crucial neurotransmitter that regulates various human behavioral processes, including mood, perception, memory,



anger, aggression, fear, stress response, appetite, addiction, and sexuality. The expression of multiple serotonin receptors in brain regions, such as the cortex, limbic system, mid-brain, and hind brain, orchestrates these processes.

Administration during Lactation:

It is expected that Escitalopram will be excreted into human milk. Consequently, breast-feeding is not recommended during treatment.

Data from the published literature report the presence of escitalopram and desmethylescitalopram in human milk.

There are reports of excessive sedation, restlessness, agitation, poor feeding and poor weight gain in infants exposed to escitalopram, through breast milk

There are no data on the effects of escitalopram or its metabolites on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Escitalopram Capsules and any potential adverse effects on the breastfed child from Escitalopram Capsules or from the underlying maternal condition.

Labeled information:

According to Summary of product Characteristics (SmPC), it was stated under section of Fertility, pregnancy and lactation stated that: "It is expected that Escitalopram will be excreted into human milk. Consequently, breast-feeding is not recommended during treatment.

Local Case Safety Report: A parent child report of excessive sleep Following maternal administration of Escitalopram

Recommendations for healthcare professionals:

- Consider Lactation Status Before Prescribing

Always assess breastfeeding status prior to initiating escitalopram or other SSRIs in women of childbearing age.

Avoid prescribing escitalopram during breastfeeding unless the expected benefit clearly outweighs the potential risk to the infant, in line with the Summary of Product Characteristics (SPC).

- Inform and Counsel Breastfeeding Mothers

Inform patients that escitalopram is excreted into breast milk and may cause adverse reactions in breastfed infants including excessive sedation, restlessness, agitation, poor feeding, and poor weight gain.

Ensure patients are educated to promptly report any behavioral or feeding changes in their infants.

- Use Risk-Minimization Strategies When Treatment Is Necessary

If escitalopram is considered essential during lactation, use the lowest effective dose.

Avoid initiating treatment at bedtime if excessive infant sedation is a concern, as maternal peak concentrations may coincide with prolonged infant exposure.

Monitor Breastfed Infants Proactively

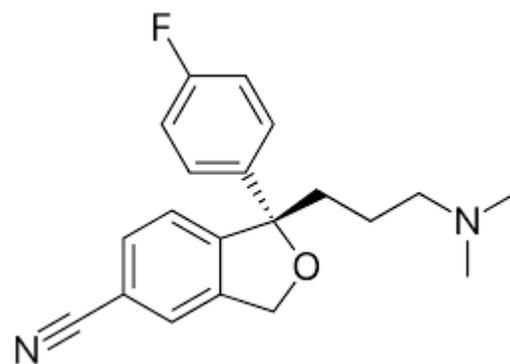
Advise close clinical monitoring of breastfed infants exposed to escitalopram for signs of central nervous system depression or feeding difficulties.

Encourage routine follow-up of infant weight gain and developmental milestones.

- Consider Safer Alternatives

Where clinically appropriate, consider alternative non-pharmacological treatments or medications with a more favorable safety profile during breastfeeding.

Reassess treatment choice if the primary indication is insomnia rather than a psychiatric disorder.



References

1. *Escitalopram SMPC* [Click here](#)
2. *Pubmed*: [Click here](#)
3. *FDA*: [Click here](#)
4. *WHO*: [Click here](#)

EPVC Participates in a scientific webinar titled "Ensuring Supplement and Drug Safety in Egypt" 2026

In alignment with focus on "Pharmacovigilance in herbal medicine" and following the "recent publication of EPVC newsletter on herbal ICSRs", EPVC participated in a scientific webinar titled "Ensuring Supplement and Drug Safety in Egypt," hosted by the Egyptian Nutrition & Health Coaching Association (ENHCA).

EPVC addressed the importance of pharmacovigilance (PV) and demonstrating the vital role of PV in Herbal medicine for ensuring safety throughout the product lifecycle, in addition to a comprehensive overview of pharmacovigilance and the national efforts to monitor Adverse Drug Reactions (ADRs).

During The event EDA representative focused on the importance of promoting a culture of reporting adverse drug reactions and highlighted national efforts to ensure drug safety and monitor adverse effects, thereby enhancing confidence in the healthcare system and achieving optimum patient safety.

Also, the presenter simulated how to report ADRs through the official EDA website and guided participants on how to access the latest safety alerts and newsletters that are launched by PVGA aimed to promote a culture of reporting adverse drug reactions and raise awareness of pharmacovigilance among healthcare practitioners in healthcare institutions.

Vigitest Competition 2026 – has come back with Live Pharmacovigilance Challenge

Following the successful launch of Vigitest in 2025, where participants competed and top contributors were recognized each month, we are excited to announce the continuation of the Vigitest competition in a new, dynamic live format for 2026!

This year, Vigitest transforms from a monthly online quiz into an interactive live competition, offering participants a fresh perspective on pharmacovigilance knowledge.

Expect rapid-fire rounds and case simulations that test your PV expertise in real-time.

How to Join Vigitest 2026

1. Register your participation by submitting your name through the Google Form linked below.

- Scan the QR code or tap the link below, follow the instruction and answer the questions.

Or

- Copy the link: <https://forms.gle/PbVtjczpE3eQ67hL6>

2. Once registered, you will receive an invitation email one day before the competition, including:

- Exact date and time of your competition round
- Instructions on accessing the live platform

This is your chance to showcase your PV skills, test your knowledge against peers, and continue the legacy of Vigitest 2025 in a live, engaging environment.

Don't miss the opportunity to be part of the Vigitest Game 2026 – where knowledge meets action!



EPVC Concludes the 7th Wave of “Together for Safe Medicine” Initiative

EPVC is extremely proud to announce the successful conclusion of the 7th wave of the initiative “Together for Safe Medicine” on 1 November 2025.

Following a comprehensive evaluation process, the EPVC team carefully reviewed and assessed participants’ activities to select the Top Achievers of this wave. We are pleased to recognize the following outstanding participants:

Top Achievers – 7th Wave

First Place: Dr. Laura Gamal – Community Pharmacy Dr. Samy Fahmy, Minya Governorate

Second Place: Soha Tawfik – Tanta General Hospital, Gharbia Governorate

Third Place: Sahar Abd Elhakim – El-Mahalla Fever Hospital, Gharbia Governorate

Fourth Place: Gehad Mohamed – Abo Abdallah Child Health Care Unit, Beheira Governorate

Fifth Place: Sara Saleh – Mahalla General Hospital, Gharbia Governorate

Sixth Place: Enaam Shaaban – Rasheed General Hospital, Beheira Governorate

Seventh Place: Rasha Hamed – Minya Chest Hospital, Minya Governorate

Eighth Place: Basma Ali – Dakahlia Governorate

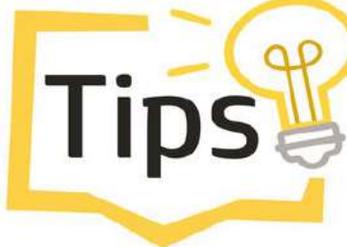
Ninth Place: Walaa Mohamed Abdul Fatah – Trabamba Health Care Unit, Beheira Governorate

Tenth Place: Hind Hamdy Naeem – Tanta General Hospital, Gharbia Governorate

EPVC extends its sincere appreciation to all participants for their dedication and commitment to promoting safe medicine practices. Your efforts continue to make a meaningful impact in strengthening healthcare awareness and patient safety across governorates.

Congratulations to all winners, and we look forward to even greater achievements in the upcoming waves of the initiative.

EPVC



On Pharmacovigilance Food and Medicine: Safety Tips

Drug exposure during pregnancy requires careful monitoring and reporting.

Keep these key PV points in mind:

- * Document gestational age and trimester – Risk varies by timing of exposure (highest during 1st trimester).
- * Capture complete drug details – Include dose, duration, indication, start/stop dates, and concomitant medications (including OTC and herbal products).
- * Record pregnancy outcomes clearly – Live birth, miscarriage, congenital anomaly, preterm birth, or neonatal complications.
- * Assess seriousness – Congenital anomalies and fetal death are always considered serious.
- * Follow up ongoing pregnancies – Update cases after delivery to obtain final outcomes.
- * Be precise in documentation – Avoid vague descriptions; use confirmed medical diagnoses whenever possible.
- * Timely and accurate reporting of pregnancy exposures strengthens drug safety monitoring and supports safer maternal and fetal health outcomes.

You can report any Adverse drug Reactions to the Egyptian Drug Authority (EDA)

Email: pv.followup@edaegypt.gov.eg

Hotline: 15301

Website: [\(click Here\)](#)

Or report through your pharmacy / product distributor / company hotline — they are required to forward it to EDA.

Why Your Report Matters

Every report submitted to us counts when it comes to the safety of medicines and patients worldwide

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](#)



One report counts

A call for reporting

Please remember that you can report safety information of medicines to EPVC using the following communication information:

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

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](#)

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: [\(click Here\)](#)



هيئة الدواء المصرية (الرعاية الصيدلانية)

