EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

IN THIS ISSUE

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EPVC
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

December 2025

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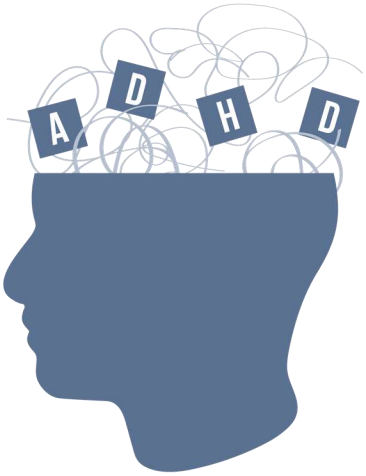
Prescriber Updater: Attention: Safety of medicines used to treat ADHD in adults

- The regulatory authority in New Zealand published the following prescriber guide whose key message is:
- Attention deficit hyperactivity disorder (ADHD) in adults is characterised by symptoms of inattention, impulsivity and restlessness resulting in functional impairment. Functional impairment includes difficulties performing everyday tasks, and reduced ability to engage in work, education or social activities. Executive dysfunction (difficulties with planning, organising, and prioritising and completing tasks) and emotional dysregulation (difficulties responding to and managing emotions) are also commonly seen.
- The predominant feature of ADHD in adults is inattention, which differs from children, where hyperactivity and impulsivity are more typical features.

Medicines used to treat ADHD in adults



Stimulant medicines block the reuptake of noradrenaline and dopamine In New Zealand, lisdexamfetamine and methylphenidate are the stimulant medicines approved for the treatment of ADHD in adults. They are indicated as an integral part of a total treatment program that may include other measures (psychological, educational and social) for patients with this syndrome. Atomoxetine is a non-stimulant medicine that inhibits the reuptake of noradrenaline. It is indicated for the treatment of ADHD in adults particularly if stimulants are contraindicated, following treatment failure with stimulants (e.g., inadequate response, problematic adverse effects), or when there is a significant risk of misuse of stimulants. Lisdexamfetamine, methylphenidate and atomoxetine have similar safety considerations.

<u>kindly note that registered products in EGYPT containing methylphenidate and Atomoxetine while lisdexamfetamine is not registered in EGYPT</u>

These are summarized in the following Table and include psychiatric effects, cardiovascular effects, risk of seizures and serotonin syndrome.

Prescriber Update: Attention: Safety of medicines used to treat ADHD in adults

Warning or precaution	Comments
Psychiatric disorders	
Comorbid psychiatric disorders	Comorbidity of psychiatric disorders in ADHD is common. Consider the patient's personal and family psychiatric history when prescribing. For example, treatment of ADHD with stimulants should not be initiated in patients with acute psychosis, acute mania or acute suicidality.
Suicidal tendency	Do not initiate treatment in patients with signs of suicidal tendency. Monitor patients for signs of suicidality, particularly during the first few months of treatment and with any dose changes.
Tics or Tourette's syndrome	Do not use lisdexamfetamine in individuals with tics or Tourette's syndrome. Methylphenidate is associated with the onset or exacerbation of motor and verbal tics, including worsening of Tourette's syndrome. There have been reports of tics with atomoxetine.
Aggressive behaviour	Monitor patients for onset or exacerbation of aggressive behaviour which may occur during treatment. Dose increases or decreases may be needed.
Cardiovascular disease	
Cardiovascular disorders	Sudden deaths have been reported with the use of stimulant medicines in patients with structural cardiac abnormalities, but a causal relationship has not been established. Adults with structural cardiac abnormalities or other serious cardiac problems (eg, cardiomyopathy, heart rhythm abnormalities) should not be treated with these medicines. Before prescribing, assess for pre-existing cardiovascular disorders, family history of sudden death and arrythmias, and measure blood pressure and heart rate. Regularly review blood pressure and cardiovascular status during treatment.
Increases in blood pressure or heart rate	Some patients can have clinically relevant increases in blood pressure or heart rate. Be careful when treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate.
Other	
Seizures	Stimulant medicines may lower the convulsive threshold in patients with or without prior history of seizure. Seizures have been reported during atomoxetine treatment.
Serotonin syndrome	Serotonin syndrome may occur following coadministration with serotonergic medicines, including selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs). If coadministration cannot be avoided, exercise caution and monitor for signs and symptoms of serotonin syndrome.
Risk of abuse (stimulant medicines)	There is potential for misuse, abuse, dependence, or diversion of stimulant medicines. Assess the risk of abuse before prescribing and monitor for signs of abuse and dependence during treatment.
Liver injury (atomoxetine)	Reports indicate atomoxetine may cause severe liver injury, including acute liver injury, elevated hepatic enzymes, and bilirubin with jaundice.

References

Local Case Safety Report: A case of non-compliance

Reason for publishing

The Regional Center of Pharmacovigilance in Cairo received a case of carpopedal spasm, perioral tingling, QT prolongation, impaired mobility, and hypocalcemia resulting from missed doses of calcium supplements and levothyroxine in a post-thyroidectomy patient.

This case concerning a fifty years old female adult patient with history of total thyroidectomy She presented to the hospital with severe symptomatic hypocalcemia (Ca = 5 mg/dL), carpopedal spasm, Perioral tingling, inability to walk and prolonged QT on ECG due to poor adherence to calcium supplementation and low-dose levothyroxine therapy.

Background:

Thyroidectomy is a surgical procedure involving the resection of the thyroid gland that can be classified into 2 main types: total thyroidectomy, which refers to the complete removal of the thyroid gland, and partial thyroidectomy, which includes procedures such as thyroid lobectomy. Thyroidectomy is indicated for a variety of conditions, including benign disorders such as multinodular goiter, toxic adenomas, and thyroiditis, as well as malignant conditions, including differentiated thyroid carcinoma and anaplastic thyroid carcinoma

Thyroid hormone supplementation

Patients who undergo total thyroidectomy for benign disease are typically started on a daily dose of levothyroxine at approximately 1.6 mcg/kg body weight after surgery. Patients over 65 years should be started at a lower dose; men may require higher doses than women.

Hypocalcemia/hypoparathyroidism :

Hypocalcemia is one of the most common complications of thyroidectomy [120]. Symptoms of hypocalcemia range from mild (eg, paresthesias around the lips, mouth, hands, and feet) or moderate (eg, muscle twitches or frank cramps) to severe (eg, trismus or tetany). Transient hypoparathyroidism has been reported in 0.3 to 49 percent of patients after thyroidectomy; up to 13 percent of post-thyroidectomy hypoparathyroidism becomes permanent.

Calcium supplementation

Calcium supplementation after thyroid surgery is typically given orally as calcium carbonate, 1250 to 2500 mg daily total, divided in two to four doses, with the starting dose adjusted and eventually tapered off based on symptoms and/or calcium levels. Patients who take a proton pump inhibitor or have had

Labeled information:

According to levothyroxin Summary of product Characteristics (SmPC) [1] it was stated that: "For treatment to be successful, levothyroxin must be taken regularly at the prescribed dosage, if treatment is interrupted or ended too soon symptom of illness may therefore return"

Recommendations for Healthcare Professionals:

- Provide clear written dosing schedules for the prescribed medication before discharge.
- Initiate prophylactic oral calcium supplementation immediately post-thyroidectomy (per institutional protocol).
- Consider adding vitamin D prophylactically in patients post Total thyroidectomy
- Encourage use of:
  - Pill organizers
  - Phone reminders
  - Mobile health apps
- To remind the patients of taking their supplementation
- · Educate the patient to take levothyroxine on an empty stomach and separate calcium by ≥4 hours to prevent absorption interference.
- Monitor for clinical manifestations of hypocalcemia, including perioral tingling, numbness, muscle twitches, carpopedal spasm, and in severe cases, seizures, EKG changes (QT prolongation), or bronchospasm.

References

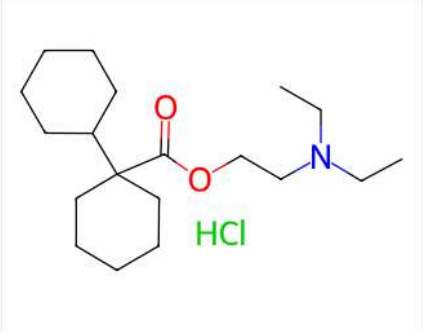
1. ***Levothyroxine SmPC*** (Click here)
2. ***EMC :*** (Click here)
3. ***Thyroidectomy :*** (Click here)
4. ***Pubmed :*** (Click here)

Safety Signal : Seizures in Breastfed Infants due to Mothers' use of Dicyclomine-Containing Products

The Safety Signals Management Unit, in the Pharmaceutical Vigilance General Administration (PVGA), identified three case reports for infants from 4 to 12 months who suffer from seizures associated with the administration of their nursing mother's dicyclomine-containing product within the normal dose as labeled in product labelling information, with an emphasis on assessing causality and potential risk factors.

Background

Dicyclomine HCl is a muscarinic M1, M3, and M2 receptor antagonist as well as a non-competitive inhibitor of histamine and bradykinin used to treat spasms of the intestines seen in functional bowel disorder and irritable bowel syndrome. Though it is commonly prescribed, its recommendation may have been based on a small amount of evidence, and so its prescription is becoming less favorable (1). A seizure represents the uncontrolled, abnormal electrical activity of the brain that may cause changes in the level of consciousness, behavior, memory, or feelings (2).



Methodology

A quantitative signal of disproportionate reporting (SDR) using the information component measure (IC) between dicyclomine-containing products and seizures in breastfed infants. A review of three reported cases, retrieved from the WHO global database of adverse event reports for medicines and vaccines (VigiBase), including literature findings, strengthens a causal association, as dicyclomine can be excreted into breast milk and reach the infant.

Results

A total of three domestic cases were retrieved from VigiBase, involving infants aged 4 to 12 months who developed seizures following maternal use of dicyclomine-containing products during breastfeeding. All cases reported by pharmacists; all cases were serious with positive de-challenge. Considering that the dicyclomine-containing products' labeling information didn`t mention a warning about the administration of dicyclomine during breastfeeding. Additionally, there are reports that administration of dicyclomine hydrochloride syrup to infants has been followed by serious respiratory symptoms (dyspnea, shortness of breath, breathlessness, respiratory collapse, apnea, asphyxia), seizures, syncope, pulse rate fluctuations, muscular hypotonia, coma, and death (3). No causal relationship has been established between the observed effects in infants and the administration of dicyclomine. Dicyclomine is contraindicated in infants less than 6 months of age and in nursing mothers, as mentioned in the FDA-approved dicyclomine label (4).

Conclusion and recommendation for actions

The weighted available evidence from the case series analysis and literature review indicates a potential safety signal of seizures in breastfed infants associated with maternal use of dicyclomine-containing products.

Accordingly, the PVGA has imposed risk-minimization measures to enhance healthcare professionals' awareness that dicyclomine-containing products are contraindicated in breastfeeding mothers and in infants younger than 6 months of age. In addition, Marketing Authorization Holders (MAHs) of dicyclomine-containing products are requested to update the product labeling to include a clear warning against use during breastfeeding and in infants under 6 months of age.

References

1. Dicyclomine SmPC: (Click here)

2. NCBI : (Click here)

3. Dicyclomine ADRs: (Click here)

4. CYCLOMINE HYDROCHLORIDE :(Click here)

EPVC Participates in the 5th Annual Conference on Excellence in Pharmaceutical Care at the Specialized Medical Centers Authority (EPAC) 2025

PVGA presented a comprehensive overview of pharmacovigilance, titled "PV landscape" which reviewed pharmacovigilance activities at the national level. The presentation 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.

The conference was organized by the Specialized Medical Centers Authority (SMC), and was held under the patronage of His Excellency the Minister of Health, Dr. Khaled Abdel Ghaffar.

During the session, PVGA presented the progress on the "BE Vigilant" initiative 2025, that launched by EPVC. This initiative aims to promote a culture of reporting adverse drug reactions and raise awareness of pharmacovigilance among healthcare practitioners by training and developing central focal points in healthcare institutions.

The conference witnessed a high-level attendance, 250 healthcare providers including members of the SMC pharmaceutical inspection department, managers and deputy managers of hospitals, and a distinguished group of members of representative' syndicates and pharmacists.

This participation emphasized the importance of the partnership with PVGA and SMC, noting that this collaboration represents a successful model of integration among government entities to provide high-quality and safe pharmaceuti-

EPVC Participates in the Scientific Day of the Department of Pharmacognosy and Medicinal Plants, Faculty of pharmacy-Pharos University

Egyptian Drug Authority (EDA), through the Egyptian Pharmacovigilance Center (EPVC) under the Central Administration for Pharmaceutical Care, participated in the Scientific Day of the Department of Pharmacognosy and Medicinal Plants held in the Faculty of pharmacy-Pharos University

EPVC presented a Lecture on “Pharmacovigilance in herbal medicine” introducing Pharmacovigilance principles, addressing the importance of pharmacovigilance and demonstrating the role of PV in Herbal medicine for ensuring their safety.

The event witnessed high presence for number of faculty members and teaching assistants, under the patronage of Professor Dr. Maged El-Ghazouly, Dean of the Faculty, and under the supervision of Assistant Professor Samar Bassam, Acting Head of the Department of Pharmacognosy

VigiTest Competition: VigiTest Competition: The 2025 Challenge is Complete!

Our heartfelt thanks for your dedicated participation in the VigiTest Competition. Your commitment, effort, and contributions are truly commendable and deeply appreciated.
We received responses from participants across various facilities, yielding a remarkable score and an outstanding accomplishment that we are thrilled to recognize.
For everyone who took part, your involvement not only showcases your skills but also plays a vital role in helping us refine and improve our processes. We deeply value your time and look forward to partnering with you on future activities.
A huge congratulations to the participants who achieved an impressive score. Your exceptional accomplishment made this initiative a success. Thank you once again!
The first 4 participants who got an impressive score and submitted their responses for whole rounds since starting VigiTest Competition:

Name	Affiliation	Title
Reem Khalil Mohammed	Qena Oncology Center, SMC	PV specialist
Nourhan Mahrous Fetoh	Kafr Elsheikh University Hospital, SCOUH	PV specialist
Alaa Awad-Allah Elgnainy	Qualified Person Responsible for Pharmacovigilance	QPPV
Soha Tawfik Abdel-Hameed	Tanta General Hospital	PV specialist

Your Certificate of Appreciation for participation and outstanding performance is on its way to your email inbox!
Seeing the brilliant minds and exceptional participation this year has fueled our excitement to keep the challenge alive!
Get ready: The next VigiTest Challenge for 2026 is right around the corner. Don't miss out!

The answers of R5 are:
1. De-challenge is the withdrawal of a medicine from a patient; the point at which ……
The Answer is: All of the above. The continuity of adverse effects may be observed, the reduction of adverse effects may be observed and the disappearance of adverse effects may be observed.

2. Positive De-challenge is the withdrawal of a medicine from a patient; the point at which ……
The Answer is: c & b. The reduction of adverse effects may be observed and the disappearance of adverse effects may be observed.

3. Negative De-challenge is the withdrawal of a medicine from a patient; the point at which ……
The Answer is: the continuity of adverse effects may be observed.

4. Re-challenge is the point at which a medicine is again given to a patient after its previous withdrawal.
The Answer is: True.

5. Positive Re-challenge is the point at which a medicine is again given to a patient after its previous withdrawal and the ADR is re-appeared.
The Answer is: True.

6. **Negative Re-challenge is the point at which a medicine is again given to a patient after its previous withdrawal and the ADR is not re-appeared.**
The Answer is: True.

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EPVC Tips

On Pharmacovigilance
Patient Safety Tip

Take your medicine exactly as prescribed—the right dose, at the right time, for the full duration.

Why this is important:

- Skipping doses or stopping early may make the medicine less effective
- Taking more or less than prescribed can increase the risk of side effects
- Doctors need to know how you took your medicine to keep you safe

What you should do:

- If you feel side effects, don't stop the medicine on your own
- Talk to your doctor or pharmacist if you forget doses or have concerns
- Report any side effects you notice—even if you're not sure they're related

You can report any Adverse drug Reactions to the Egyptian Drug Authority (EDA)
Email: pv.followup@edaegypt.gov.eg
Hotline: 15301
Website: (click Here)

Your correct use of medicines helps protect your health and others.
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*

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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.

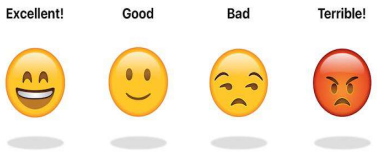
What is the Egyptian Pharmaceutical Vigilance Center?

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

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