



هَيْئَةُ الدَّوَاءِ الْمِصْرِيَّة

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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

## February 2025

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## Reminder Safety Alert : More prominent safety warnings about the neuro-psychiatric effects of Montelukast

Regulatory Authority in Australia has published More prominent safety warnings about the neuro-psychiatric effects of montelukast

### Summary

Montelukast is a prescription medicine used to prevent and treat chronic asthma in adults and children aged 2 years and older, and for symptomatic seasonal allergic rhinitis (hay fever).

Additional safety information is being added to all montelukast products to strengthen and highlight existing warnings about serious neuropsychiatric events. These include behavioral changes, depression and suicidal thoughts and behavior. The safety information includes:

1. A new boxed warning
2. Additional guidance for prescribers and patients on the management of serious neuropsychiatric events.

### What health professionals should do

Health professionals are reminded about the potential neuropsychiatric effects associated with montelukast. These effects have been reported in all age groups taking montelukast, are generally mild and may occur by chance. However, symptoms can be serious and continue if treatment is not stopped. In rare cases, patients taking montelukast have died after experiencing suicidal behavior.

Health professionals should be vigilant for neuropsychiatric reactions in patients taking montelukast and discontinue treatment if new or worsening symptoms occur.

Advise patients and their carers to be alert for changes in behaviour or for new neuropsychiatric symptoms and to seek medical advice immediately should they occur.



### References:

1. TGA: [\(Click Here\)](#)
2. Picture : [\(Click Here\)](#)





## Local Case Report

### A possible case report of drug Interaction between Levothyroxine and Orlistat

#### 1. Reason for publishing:

The regional centre in Cairo has received a case involving a female patient with hypothyroidism and obesity. The patient reported experiencing fatigue, body aches, and bone pain. Despite treatment with Levothyroxine, her thyroid symptoms persisted, suggesting decreased efficacy of the medication. Furthermore, she had initiated Orlistat for weight loss without allowing an appropriate time interval between the two treatments.

#### 2. Background:

Hypothyroidism is a common endocrine disorder resulting from deficiency of thyroid hormone.

##### Types of Hypothyroidism:

Hypothyroidism is divided into primary, secondary, tertiary, and peripheral types

Primary hypothyroidism is due to inadequate production of thyroid hormone caused by disease of the thyroid gland.

**Central hypothyroidism** (secondary or tertiary) results when the hypothalamic-pituitary axis is damaged and TSH is deficient

peripheral hypothyroidism (extra-thyroidal)

##### Levothyroxine:

Levothyroxine is synthetic thyroxine (T<sub>4</sub>) used as a replacement or supplemental therapy in congenital or acquired hypothyroidism of any etiology. Specific indications include primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) hypothyroidism

**Mechanism of action:** Synthetic T<sub>4</sub>; thyroid hormone increases basal metabolic rate, increases utilization and mobilization of glycogen stores, promotes gluconeogenesis; involved in growth development and stimulates protein synthesis

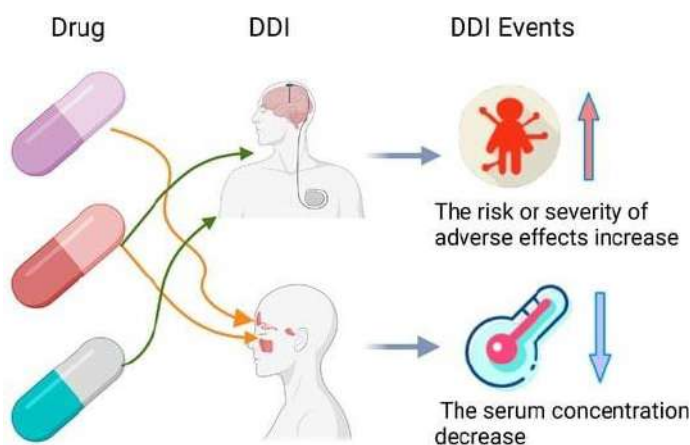
Levothyroxine monotherapy is recommended as the preferred thyroid preparation for the treatment of hypothyroidism

##### Obesity:

Overweight and obesity are defined as abnormal or excessive fat accumulation that presents a risk to health. A body mass index (BMI) over 25 is considered overweight, and over 30 is obese.

##### Orlistat:

Lipase Inhibitor used for weight loss in overweight adults when used along with a reduced-calorie and low-fat diet.



**Mechanism of action:** A reversible inhibitor of gastric and pancreatic lipases, thus inhibiting absorption of dietary fats by 30%.

##### Labeled information:

According to Levothyroxine Summary of Product Characteristics Hypothyroidism and / or reduced control of hypothyroidism may occur when Orlistat and levothyroxine are taken at the same time. This could be due to a decreased absorption of iodine salts and / or levothyroxine.

According to Orlistat Summary of Product Characteristics: Hypothyroidism and/or reduced control of hypothyroidism may occur when orlistat and levothyroxine are co-administered Patients taking levothyroxine should consult a doctor before starting treatment with Orlistat as the two medications may need to be taken at different times and the dose of levothyroxine may need to be adjusted



## Local Case Report

### A possible case report of drug Interaction between Levothyroxine

#### According to the drug interaction checker:

Moderate interaction:

**ADJUST DOSING INTERVAL:** Orlistat may interfere with the gastrointestinal absorption of levothyroxine and other thyroid hormones. The exact mechanism of interaction is unknown. In one case report, symptomatic hypothyroidism occurred within two weeks following the initiation of orlistat in a patient with thyroid cancer who had been receiving levothyroxine for 18 months to suppress thyroid-stimulating hormone production after a total thyroidectomy and radioiodine ablation. The patient complained of tiredness, lethargy and cold intolerance, and thyroid function tests revealed profound hypothyroidism. Symptoms improved two weeks following the discontinuation of orlistat and an increase of levothyroxine dosage from 250 to 300 mcg/day. Laboratory values returned to normal another two weeks later.

**Orlistat and oral thyroid hormone preparations should be administered at least 4 hours apart. Close clinical and laboratory monitoring of thyroid func-**

#### References

1. *Hypothyroidism: Practice Essentials* ([click here](#))
2. *Levothyroxine: Drug information* ([click here](#))
3. *Epidemiology, Types, Causes, Clinical Presentation, Diagnosis, and Treatment of Hypothyroidism* ([click here](#))
4. *WHO: Obesity* ([click here](#))
5. *Orlistat: Drug information* ([click here](#))
6. *Drug Interaction Report* ([click here](#))
7. *Orlistat SPCs* ([click here](#))
8. *Levothyroxine SPCs* ([click here](#))



## “Together for Safe Medicine” Initiative News:

The Egyptian Drug Authority (EDA) took part in a drug safety event organized by the Drug Information and Pharmacovigilance The Egyptian Drug Authority has announced the start of the seventh wave of the "Together for Safe Medicine" Initiative which is a free initiative delivered by the Egyptian Pharmaceutical Vigilance Center -Central Administration of Pharmaceutical Care.

"Good health and wellbeing" is one of the Global Sustainable Development Goals (SDGs) and Health Pillar in Egypt Vision 2030

that this initiative aims to achieve. The objective is to promote pharmacovigilance expansion and excellence throughout Egypt, whether among the public or Healthcare Professionals (HCPs). Improving community pharmacies' involvement in PV procedures and encouraging more spontaneous reports from public are essential for promoting safe and effective medication and hence patient safety. A multidimensional win is establishing a network of community pharmacies in an ongoing partnership with EDA as well as Establishing a strong public-EDA network and promoting reporting through many channels, including E-reporting, EDA hotline, Arabic link on EDA Website.

Those pharmacies have a great opportunity to obtain a competitive edge thanks to EDA. At the end of the initiative wave, EDA will certify and recognize the pharmacy and the pharmacist for their efforts.

For registration, please click the following link: <https://shorturl.at/KTTyF> or scan the following QR Code.



## Egyptian Pharmaceutical Vigilance Center (EPVC) Vigiflow expansion project

Egyptian Pharmaceutical Vigilance Center (EPVC) expresses gratitude to the Ministry of Health and Population (MoHP) for enhancing pharmacovigilance practices within its organizations. So, EPVC commends the following MoHP organizations for their high ICSR entry rate on Vigiflow: "Giza Health Directorate, Cairo Health Directorate, Menofia Health Directorate, Gharbia Health Directorate, Beheira Health Directorate, Al Sharkia Health Directorate, Dakahlia Health Directorate, Assiut Health Directorate, Al Mamoura chest Hospital".

EPVC also wants to thank the following organizations: "Damanhour Oncology Center, Mansoura International Hospital" for their high-quality ICSRs entered on Vigiflow and "Qena Oncology Center, Minya Oncology Center, Nasser Institute" for their high-quality and quantity ICSRs entered on Vigiflow.

EPVC is thrilled to announce the addition of “Mahalet El Marhoum Hospital” to our community. We are confident that this partnership will bring valuable contributions and enhance the well-being of those we serve together.

EPVC would like to thank the following Organisations their efforts and interest in integrating ICSRs into the Vigiflow system: 6 October HIO Hospital - Dokki, and Al Mansoura HIO Hospital. Your active participation in the national database reporting system is essential and highly valued. Your contributions play a crucial role in ensuring the system's effectiveness and reliability.

The EPVC wishes to thank the Egyptian Health Care Authority (EHA) for the high quality of Individual Case Safety Reports (ICSRs) submitted to VigiFlow. We appreciate the efforts made by EHA organizations to promote pharmacovigilance. Additionally, EPVC extends special thanks to the Port Said EHA for the significant quantity and quality of Individual Case Safety Reports they have entered into VigiFlow.





## VigiTest Competition Answers :

First we would like to thank all of you for efficiently participating in our vigitest Competition, we really appreciate it, your dedication and efforts are truly commendable. We had **90 responses** from participants of different facilities with **62** who got full score which is considered an outstanding accomplishment!

For all of you who participated your contribution not only demonstrates your skills but also helps us improve and refine our process, we are grateful for your time and commitment and we are looking forward to your continuous participation in the future. And for all of you who got full score we sincerely congratulate you on your perfect score and thank you for being a valuable part of this initiative.



**The thalidomide tragedy of the late 1950s and early 1960s is widely regarded as a turning point in pharmaceutical regulation. What was the primary cause of this tragedy?**

The Answer is: **Inadequate testing for safety during pregnancy** caused this tragedy. The thalidomide tragedy occurred because the drug, used as a sedative and treatment for morning sickness, was not tested for teratogenic effects. This led to severe birth defects in thousands of children.

**What is the primary purpose of pharmacovigilance?**

The Answer is: to **monitor the safety of drugs after they are approved for use**. Pharmacovigilance is focused on identifying, assessing, and preventing adverse effects of drugs once they are on the market. This is critical because even after regulatory approval, drugs may pose risks that were not evident during clinical trials.

**Which of the following is NOT a recommended practice when collecting data on an adverse drug reaction (ADR)?**

The Answer is: **Collecting only subjective descriptions of symptoms**. Objective clinical data is necessary when reporting ADRs, such as lab results, specific details of the drug dose, and time of onset of symptoms. Relying only on subjective descriptions can lead to incomplete or inaccurate reports.

**What is a "Signal" in pharmacovigilance?**

The Answer is: **An indication of a potential new risk associated with a drug based on collected data**. A signal refers to information that suggests a new or previously unknown risk associated with a drug, based on a collection of data, such as adverse event reports, that merits further investigation.

**Spontaneous reporting of Adverse drug reactions (ADRs) is voluntary and blame free?**

The Answer is: True



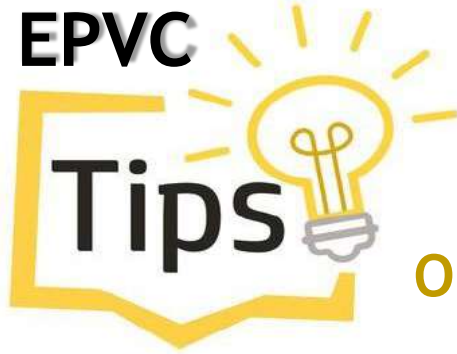
## VigiTest Competition Winners:

The first 10 participants who got full score and submitted their responses first:

Thank you once again for your valuable contribution. Your dedication and effort are highly appreciated, and we encourage you to continue the excellent work you've been doing. Your commitment and professionalism significantly enhance the success of our team, and we look forward to seeing your continued growth and success.

Name	Affiliation	Title
Sara Saleh Moustafa Ragab	Mahalla general hospital	Hospital Pharmacist
Wessam Mahmoud Mohammed	Cairo University Specialized Pediatric Hospital	Hospital Pharmacist
Mazen Mohamed Sobhi El seadi	Shubin El-Kom Fever Hospital	PV specialist
Reem Khalil Mohammed Khalil	Qena oncology center	PV specialist
Mariam George Fawzy	Shubra general hospital	Hospital Pharmacist
Naglaa Fathi Mohamed Badri	Kom Elshoqafa chest hospital	Hospital Pharmacist
Naly Shaker Mina Samaan	Primary care pharmacist at the DIC, Abu Qir2 unit, Montazah medical district	Clinical Pharmacist
Nermin Nabil Naguib	Pharmacovigilance officer in Shubra General Hospital	PV specialist
Ismaiel Korany Ali	Scope Medical for Import and Export	Employee
Heba Mahmoud Mahmoud	Pyramid health administration	Community Pharmacist





## On Pharmacovigilance

### Tips on Medication Safety

1. Follow the Five Rights: Right patient, right drug, right dose, right route, right time.
2. Check for Drug Interactions
3. Read Labels & Instructions: Ensure correct dosage, storage, and administration.
4. Avoid Polypharmacy Risks: Review medications regularly, especially in elderly patients.
5. Report Adverse Reactions Promptly: Use pharmacovigilance systems (e.g., FDA MedWatch, WHO Uppsala).
6. Prevent Medication Errors: Double-check prescriptions, confirm patient allergies, and educate patients.



**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 .

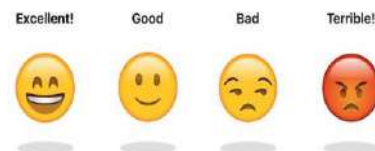
EPVC monitors the safety of all types of pharmaceutical products, including human medicines, biological products, supplements, cosmetics, veterinary medicines, medical devices, Biocides and pesticides

### 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)



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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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