



هَيْئَةُ الدَّوَاءِ الْمِصْرِيَّة

IN THIS ISSUE

DHPC : Thiocolchicoside containing medicines for systemic use: -important information on restrictions associated with the risk of genotoxicity 1

Local case report Terbutaline Sulfate may exacerbate preexisting diabetes 2

EPVC News 3-4

EPVC Tips 5

Prepared by:

Reem Tarek
Salma Radwan
Esraa Abd Elhamid
Medhat Abd Elhakam
Lobna Samy
Mariam Morkos
Maysa Hussien

Designed by:

Reem Tarek

Chief Editor

Maha Mohamed

Head of Egyptian
Pharmacovigilance Center

Under supervision of

Yassin Ragaey

EDA Assistant chairman for
Media Affairs and Investment
Support and Supervisor of the
Central Administration for Phar-
maceutical Care



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

March 2025



Volume 16

Issue 3

DHPC : Thiocolchicoside containing medicines for systemic use: - important information on restrictions associated with the risk of genotoxicity

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance (PVGA) at the Egyptian drug authority (EDA) would like to Inform you about important information on restrictions associated with

the risk of genotoxicity

Summary:

Contraindications for use of thiocolchicoside containing medicines for systemic use have been updated, and contraceptive measures have been extended.

Thiocolchicoside containing medicines are contraindicated and should not be used:

In male patients who do not wish to use effective contraceptive measures during treatment with systemic thiocolchicoside and for 3 months after discontinuation of thiocolchicoside

In female patients of childbearing age who are not using effective contraceptive methods during treatment with systemic thiocolchicoside and for 1 month after stopping

Thiocolchicoside. Thiocolchicoside for systemic use remains contraindicated also in women of childbearing age who do not use effective contraceptive methods during treatment and in pregnant and breastfeeding women.

The updated information is being implemented in the respective medicinal product leaflets

Background on the safety concern

As already known, the results of preclinical studies have indicated a risk of genotoxicity related to the metabolite of thiocolchicoside for systemic use (i.e. oral and intramuscular forms).

In particular, in preclinical studies it has been shown that one of the metabolites of thiocolchicoside induces aneuploidy at concentration levels close to those observed in humans following the

maximum recommended oral dose of 8 mg twice daily. Aneuploidy is considered a risk factor for teratogenicity, embryo/fetal toxicity, spontaneous abortion and reduced male fertility

and a potential risk factor for tumors.

The risk increases with long-term exposure and at high doses. For this reason, the medicine is already contraindicated in women of childbearing age who do not use contraceptive measures, and in pregnant and breastfeeding women. Now the contraindication has been extended to:

-Men who are not willing to use effective contraceptive measures during treatment and for 3 months after stopping treatment, to avoid conception and any consequent risks to the fetus;

-Women of childbearing age who do not use effective contraceptive methods even for 1 month after stopping treatment, to avoid pregnancy and any consequent risks for the fetus.

The new information follows the recommendations of the guideline of the Safety Working Party (SWP, now Non-clinical Working Party (NcWP)) of the European Medicines Agency (EMA) on the duration of contraception following the end of treatment with drugs with a known risk of genotoxicity.

Healthcare professionals are reminded that the use of systemic thiocolchicoside is limited to the short-term adjuvant treatment of painful muscle contractions in acute spinal disorders in adults and adolescents aged 16 years and older. The maximum recommended daily doses and duration of treatment are, respectively, 16 mg per day for up to 7 days orally, 8 mg per day for up to 5

days intramuscularly.

References:

1. AIFA: [\(Click Here\)](#)
2. DHPC: [\(Click Here\)](#)





Local Case Report

Terbutaline Sulfate may exacerbate preexisting diabetes

1. Reason for publishing:

The Egyptian Pharmaceutical Vigilance Centre has received a case report, its details as following:

A 50-year-old male, who has a medical history of diabetes mellitus.

He started to administer a suspect medication containing Terbutaline sulphate as a bronchodilator orally for 15 days. he developed hyperglycaemia, and reaction was serious as it led to hospitalization.

Upon follow up, it was found that, patient blood glucose level increased to 400 mg/dl, and he was admitted to hospital. Reaction was serious and recovered as reported.

Background

Hyperglycemia:

Hyperglycemia is the technical term for high blood glucose (blood sugar). High blood glucose happens when the body has too little insulin or when the body can't use insulin properly.

Labeled information:

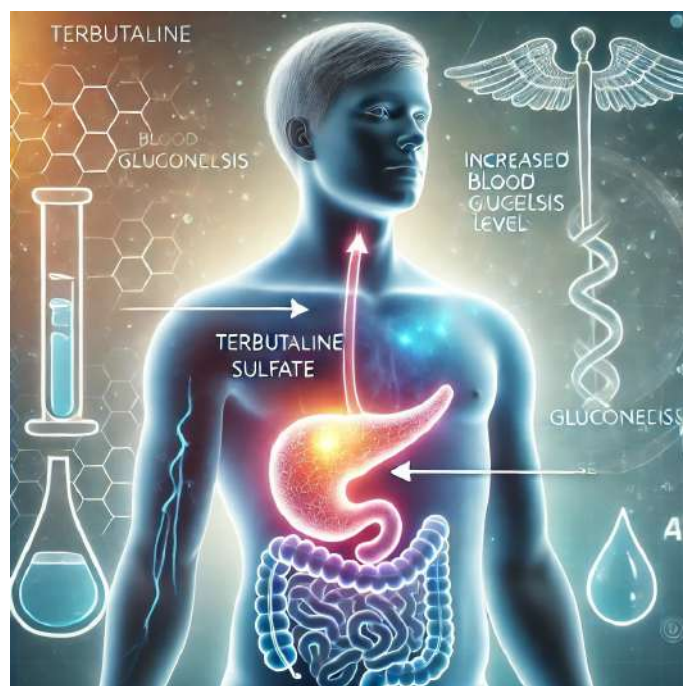
Terbutaline sulfate: beta 2 agonist

Mechanism of Action

- Relaxes bronchial and uterine smooth muscle by action on beta2-receptors with less effect on heart rate

Adverse Reactions

- Endocrine & metabolic: More than 10 % of cases may experience increased serum glucose level
- Due to the hyperglycemic effects of beta2-agonists, additional blood glucose controls are recommended initially in diabetic patients.
- Use with caution in patients with diabetes mellitus; beta2-agonists may increase serum glucose and aggravate preexisting diabetes and ketoacidosis.



References

1. Bronchodilator containing Terbutaline sulfate leaflet ([click here](#))
2. UpToDate: Terbutaline: Drug information ([click here](#))
3. Hyperglycemia (High Blood Glucose) ([click here](#))



Egyptian Pharmaceutical Vigilance Center (EPVC) Vigiflow expansion project:

The Egyptian Pharmaceutical Vigilance Centre (EPVC) expresses gratitude to the Ministry of Health and Population (MoHP) for enhancing pharmacovigilance practices among its organizations and for their high input rate of Individual Case Safety Reports (ICSR) on Vigiflow.

The Egyptian Pharmaceutical Vigilance Center (EPVC) thanks the Egyptian Health Care Authority (EHA) for their outstanding efforts in enhancing pharmacovigilance within their organizations and for the high quality of Individual Case Safety Reports (ICSRs) submitted on Vigiflow.

In line with this, EPVC is pleased to present a webinar on "Areas of improvement and underreporting" with focal points from Specialized Medical Center (SMC) Supreme Council of University Hospitals (SCUH).

We really value your participation in the national database reporting system. Additionally, EPVC would like to express its gratitude to all of the organizations that collaborated with us to expand the Vigiflow system. We wish them ongoing success in their work and commend their dedication to improving the monthly section cases and the increasingly better case quality stages in the national database.

“Together for Safe Medicine“ Initiative News:

The Egyptian Drug Authority has announced the results of selecting the Top 10 pharmacists from the fifth and sixth waves of the "Together for Safe Medicine" initiative. This initiative aims to promote and implement pharmacovigilance practices and encourage the reporting of adverse drug reactions in the Egyptian market, ensuring safer and more effective medications for citizens.

Planned in six waves, the initiative has now successfully completed its first six phases, with 482 pharmacists from private pharmacies and hospital outpatient pharmacies across 27 governorates participating. These pharmacists have played a vital role in increasing the number of adverse drug reaction (ADR) reports submitted to the Egyptian Vigilance Center.

The Top 10 pharmacists were selected based on their exceptional contributions to spreading pharmacovigilance awareness, submitting the highest number of ADR reports, and engaging in various outreach activities such as posters, educational materials, social media campaigns, and awareness lectures. Additionally, they leveraged modern tools like AI-generated awareness videos and podcasts to expand their impact.

Their efforts have significantly contributed to increasing public and healthcare professionals' awareness of drug safety, utilizing platforms like YouTube and social media to reach a broader audience. As a result, the most distinguished pharmacists from government hospitals and private pharmacies were recognized for their outstanding achievements in the fifth and sixth waves.



VigiTest Competition: The Challenge Continues!

Healthcare heroes, the excitement is far from over! The VigiTest competition is back for another round, and it's time for you to sharpen your pharmacovigilance skills once again.

We've seen incredible participation and brilliant minds in our first round, but the journey is just beginning. Each month, we'll continue to challenge your knowledge of pharmacovigilance principles and science. Are you ready to join?



How to Join: It's simple. Scan the QR code provided in the newsletter or tap the link below to access the competition questions. Answer correctly with your knowledge and skill, and you could be one of our monthly winners. **Monthly Winners:** Every month, the top participants will be celebrated for their expertise.

Annual Winners: At the end of the year, the top consistent winners will be recognized for their brilliance throughout the year and win certificate of appreciation for their participation and outstanding performance. Follow the next release, and stay tuned for the results and winners

The competition is ongoing, and the next challenge is waiting for YOU. Don't miss out.

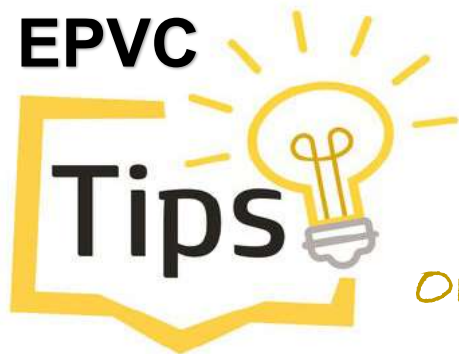
Tap the link below :

<https://forms.gle/ZgQ5PWdbKhSCWWPDA>

Or Scan the QR code :

follow the instruction and answer the questions.





On Pharmacovigilance

Pharmacovigilance Tip: Understanding the Risk-Benefit Balance

Every medication undergoes rigorous evaluation before approval, but real-world use can reveal new safety concerns. Pharmacovigilance plays a critical role in continuously assessing a drug's risk-benefit balance by monitoring adverse events and updating safety measures.

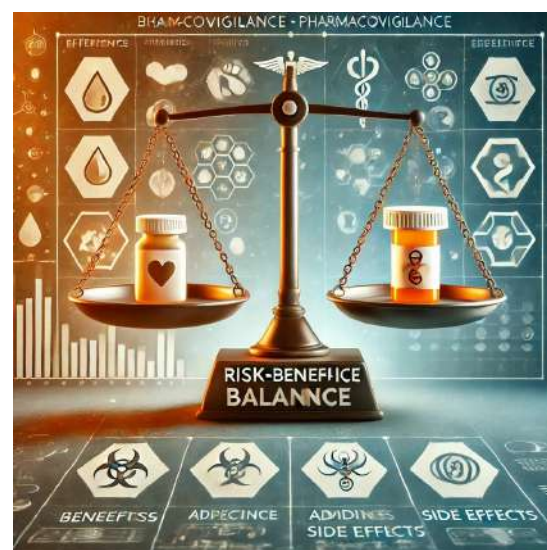
Risk: Potential adverse effects, interactions, and contraindications.

Benefit: The therapeutic effect and overall improvement in patient health.

To ensure patient safety:

1. Monitor and report any suspected adverse drug reactions (ADRs).
2. Assess whether the benefits still outweigh the risks for each patient.
3. Stay updated with safety alerts and regulatory changes.
4. Encourage informed decision-making by educating healthcare professionals and patients.

By proactively balancing risks and benefits, pharmacovigilance ensures that medications remain safe and effective throughout their lifecycle.



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.

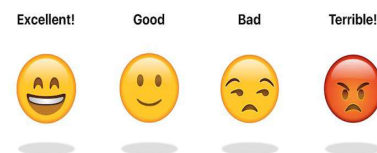


Participate with us

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)



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

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: www.edaegypt.gov.eg

<https://sites.google.com/view/epvc-reporting/healthcare-professional-public-adverse-drug-event-reporting/reporting-other-adverse-drug-event-cases>



هيئة الدواء المصرية (الرعاية الصيدلانية)