EGYPTIAN DRUG AUTHORITY

هيئة الدواء المصرية

The Egyptian Pharmaceutical Vigilance center

مركز اليقظة الصيدلية المصري

IN THIS ISSUE

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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

May 2025

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Local Case Report

Colistimethate sodium induced Bartter's syndrome

1. Reason for publishing:

The regional centre in Cairo has received a case involving an elderly female patient. She started to administer Colistimethate sodium with a dose of 4.5 million intravenously every 12 hours for sepsis. On 10/02/2025, she developed Bartter-like syndrome with polyuria and hypocalcemia. Reaction was serious as it led to hospitalization. Colistimethate sodium was withdrawn on 10/02/2025 and reaction recovered on 12/02/2025.

2. Background:

Colistin is a polymicrobial bactericidal drug and currently re-emerged as the only salvation therapy against multidrug resistant bacilli especially in critically ill patients at intensive care units.

Mechanism of action: Colistin is a cyclic polypeptide antibacterial agent belonging to the polymyxin group. Polymyxins work by damaging the cell membrane and the resulting physiological effects are lethal to the bacterium. Polymyxins are selective for aerobic Gram-negative bacteria that have a hydrophobic outer membrane.

Bartter-like syndrome (BLS): is a constellation of biochemical abnormalities which include metabolic alkalosis, hypokalemia, hypocalcemia, hypomagnesemia with normal kidney function. BLS is a very rare syndrome and can be induced by certain diseases, antibiotics, diuretics, and antineoplastic drugs.

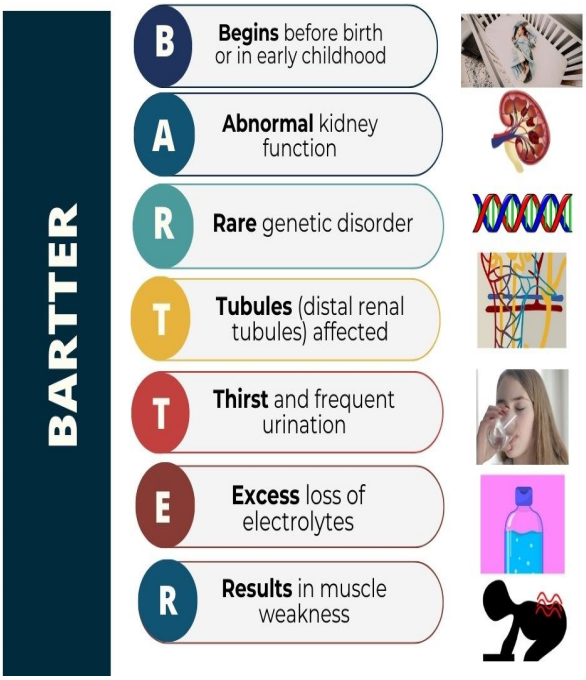
Labeled information:

According to Colistin Summary of product Characteristics (SmPC) [1] it was stated under section Special warnings and precautions for use that: Few cases of pseudo-Bartter syndrome have been reported in children and adults with the intravenous use of colistimethate sodium, Pseudo-Bartter syndrome has been reported after intravenous administration of colistimethate sodium with unknown frequency

3. Recommendations for Healthcare Professionals:

1.Monitoring of serum electrolytes should be started in suspected cases and appropriate management should be implemented.

2.Normalization of electrolyte imbalance might not be achieved without discontinuation of colistimethate sodium.



References

1. Colistin SmPC (click here)
2. Colistin-induced Bartter-like Syndrome: Ponder before Treatment (click here)
3. Colistin-induced acquired Bartter-like syndrome: an unusual cause of meltdown (click here)
4. Picture : (click here)

"Together for Safe Medicine" Initiative News:

EPVC Announces the Launch of the 7th Wave of the "Initiative Together for Safe Medicine"

The Egyptian Pharmaceutical Vigilance Center (EPVC) is proud to continue its successful journey in promoting pharmacovigilance science across all sectors of healthcare in Egypt. In its ongoing efforts to enhance medication safety and strengthen the national pharmacovigilance system, EPVC is expanding its outreach to both governmental and community pharmacists throughout Egypt's governorates.

Following the successful completion of registration for the seventh wave of the "Initiative Together for Safe Medicine" on 20 April 2025, EPVC is pleased to announce that pharmacovigilance activities for this wave are scheduled to commence in May 2025.

This initiative reflects EPVC's unwavering commitment to building capacity, raising awareness, and fostering a culture of safe medicine use across the country. Through this wave, the Center aims to empower pharmacists with the knowledge and tools necessary for effective adverse drug reaction (ADR) reporting and risk minimization practices.

EPVC looks forward to the active participation and collaboration of all stakeholders in making this wave as impactful and successful as the previous ones.

Egyptian Drug Authority Participation in TB and Chest centers Qualifying Program 2025

As part of its mission to enhance pharmaceutical care and ensure patient safety, the Egyptian Drug Authority (EDA), through its General Administration of Pharmacovigilance, is expanding pharmacovigilance efforts nationwide. The Egyptian Pharmacovigilance Center conducted five lectures in May 2025 as part of a training program for TB & Chest Centers. These sessions, titled "Pharmacovigilance and the Importance of Monitoring Adverse Events for TB Medications," aimed to qualify healthcare providers and integrate them into the national VigiFlow database. This initiative supports the National Tuberculosis Control Program and marks the beginning of a broader training rollout across all Egyptian governorates.

The training approached 85 pharmacists and nurses working in chest units in Cairo, Menoufia and Dakhleya and trained on:

1. Pharmacovigilance principles and how to monitor and record the side effects of TB medications.
2. Activating the adverse effects form, which was developed to accompany the TB patient's treatment card.
3. Expanding focal points at institutions, hospitals, and centers by registering in the Vigiflow database.

The event was held under the auspices of Prof. Wagdy Amin, Director General of the Chest Diseases Department, and Dr. Hend Ashour, Head of General Administration of Pharmaceutical Affairs at the Ministry of Health. And attended by Dr. Magda Afifi, Drugs and Procurement Officer and Pharmacovigilance Coordinator for the National Tuberculosis Control Program; Dr. Hanadi, Director of the Clinical Pharmacy Department; Dr. Maria and Dr. Mariam PV coordinators at Ministry of Health.

The activities addressed the importance of ADRs reporting that generating real-world data to achieve excellence in regulatory decisions.

This comes in light of the Egyptian Drug Authority's commitment to providing training to disseminate pharmacovigilance concepts and raise awareness of the available channels for reporting adverse drug reactions, thus contributing to ensuring the safety of pharmaceutical products and supplies in the Egyptian market.

The Egyptian Drug Authority Participates in Job Fair Event at Al Salam University

Egyptian Drug Authority (EDA), through the Egyptian Pharmacovigilance Center (EPVC) under the Central Administration for Pharmaceutical Care, participated in the Second Job Fair Event organized by the Faculty of Pharmacy, Al Salam University. The event, held under the theme "Introduction of Pharmacovigilance and the Importance of Monitoring and Reporting Adverse Drug Reactions," reflects the EDA's continuous efforts to promote pharmacovigilance awareness and practices across academic and professional settings.

The event took place under the esteemed patronage of Prof. Dr. Abdelfatah Sadka, President of Al Salam University; Prof. Dr. Mokhtar Mabrouk, Dean of the Faculty of Pharmacy; and Prof. Dr. Mohamed Abd El-Hameed, Vice-Dean of the Faculty of Pharmacy.

The EDA delivered a lecture focusing on the science of pharmacovigilance, outlining key topics such as:

- Introduction and basic principles of pharmacovigilance
- What and how to report Adverse Drug Reactions (ADRs)
- Various methods for reporting ADRs including the E-reporting portal, Arabic reporting link, and the EDA hotline
- Risk awareness regarding substandard and falsified medical products

This session was delivered in the presence of notable guests, including:

Prof. Dr. Doaa Habib, Head of the Pharmaceutical Technology Department, Al Salam University

1. Dr. Hany Fawzy, Chairman of the Gharbia Pharmacy Syndicate
2. Dr. Mostafa Salam, Chairman of the Menoufia Pharmacy Syndicate
3. Dr. Mohamed Fahmy, Chairman of the Kafr El-Sheikh Pharmacy Syndicate
4. Dr. Magde Thabet, Chairman of the Qalyubia Pharmacy Syndicate
5. Dr. Mostafa Bahgat, Chairman of the Board of Directors for Pharmaceutical Industries

The event witnessed the enthusiastic participation of approximately 950 pharmacy students, highlighting the growing interest in pharmacovigilance as a crucial area of pharmaceutical education.

Throughout the event, vibrant discussions addressed the role of pharmacovigilance in safeguarding public health, the mechanisms of ADR reporting, and the broader implications of ensuring the quality and safety of medications in the Egyptian healthcare system.

The EDA's participation underscores its commitment to fostering inter-institutional collaboration, promoting a culture of safe medication use, and empowering future pharmacists with the knowledge necessary to contribute meaningfully to public health and patient safety.

VigiTest Competition Answers :

Once again, we sincerely thank you for your valuable contribution. Your dedication and hard work are greatly appreciated, and we encourage you to keep up the excellent efforts you've shown. Your commitment and professionalism play a crucial role in the success of our team, and we are excited to witness your continued growth and achievements in the future.

The answers are:

Which of the following is an example of a 'Type A' (dose-dependent) adverse drug reaction (ADR)?

The Answer is: **Hypotension due to ACE inhibitors**, as 'Type A' ADRs, also called predictable or dose-dependent reactions, occur as a direct result of the drug's known pharmacological properties. Hypotension due to ACE inhibitors is a classic example since it's a well-known effect related to the dose of the drug.

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.

Which of the following factors is the primary reason that certain patients are more susceptible to adverse drug reactions?

The Answer is: **Genetic variations and underlying health conditions**. Genetic factors and underlying health conditions (e.g., liver or kidney disease, genetic polymorphisms) significantly influence how individuals metabolize and respond to drugs, making them more susceptible to ADRs.

What does the term "black box warning" refer to in drug labeling?

The Answer is: **A warning indicating the risk of serious or life-threatening adverse effects**. It is the most serious warning given by regulatory authorities (e.g., EDA), signaling that the drug has been shown to cause severe, potentially fatal side effects in some cases. This warning is prominently displayed on the drug's labeling.

T/F: A "serious adverse event" is defined as any adverse event that results in death, a life-threatening condition, hospitalization, disability, or requires intervention to prevent permanent damage?

The Answer is: **True.** A serious adverse event (SAE) meets one of these criteria: death, life-threatening condition, hospitalization, disability, or any condition that necessitates medical intervention to avoid lasting damage.

T/F: Post-marketing surveillance is a critical component of pharmacovigilance as it allows the detection of ADRs that may not have appeared during clinical trials?

The Answer is: **True.** Post-marketing surveillance is essential for identifying ADRs that might not have been observed during clinical trials, due to the more diverse patient population and longer exposure periods.

VigiTest Competition Winners:

We would like to extend our heartfelt thanks to each of you for your active and dedicated participation in the Vigitest Competition. Your commitment and effort are truly commendable, and we greatly appreciate your contributions.

We received responses from participants across various facilities, with a remarkable 18 achieving a perfect score an outstanding accomplishment that deserves special recognition!

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 dedication and look forward to your continued participation in the future.

Name	Affiliation	Title
Medhat Ahmed Mahfouz	Zeta Pharma	PV specialist
Nourhan Mahrous Fetoh	Kafr Elsheikh University Hospital, SCOUH	PV specialist
Reem Khalil Mohammed	Qena Oncology Center, SMC	PV specialist
Mai Elnogoly	Zeta Pharma	PV specialist
Dina Hassan El banna	New Cairo Specialized Hospital, SMC	PV specialist
Mennatallah Ashraf	EL Helal Hospital, SMC	PV specialist
Eman Ahmed Mohamed	Tanta university Hospitals, SCOUH	Hospital Pharmacist
Laura Gamal Saleh Salama	Dr. Samy Community Pharmacy	Clinical Pharmacist
Rasha mohammed nabil	Minia Oncology Center, SMC	Clinical Pharmacist
Asmaa Wardani Abdulgawwad	Specialized medical centers	PV specialist

EPVC Tips

On Pharmacovigilance

Medical Device Vigilance Tips Series

Tip 1: Report Malfunctions—Even Without Harm
Even if no injury occurred, always report device failures or malfunctions. Early reporting prevents future incidents.

Tip 2: Include the Device Details
When reporting, include the device name, model, serial/batch number, and manufacturer. These details help identify problems faster.

Tip 3: User Error Matters Too
If a device incident was caused by misuse, incorrect setup, or unclear instructions, report it! These are important for improving design and training.

Tip 4: Watch for Labeling Issues
If device instructions are confusing, missing, or mistranslated, report it as a safety concern—even if the device works fine.

Tip 5: Report to the Right Place
Know your national reporting system. In Egypt, report device incidents to the Egyptian Drug Authority (EDA) through their official channels. Ensure Proper Storage & Disposal: Store medicines correctly and discard expired drugs safely

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

Communication information

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