IN THIS ISSUE

Prepared by:
Reem Tarek
Alaa Yahya
Ola Fahmy
Esraa Salah
Lobna Samy

Designed by:
Reem Tarek

Chief Editor
Fatma Hassan
Head of Egyptian Pharmacovigilance Center

Under supervision of
Abeer El baheiry
Head of the Central Administration for Pharmaceutical Care

EPVC Mission

Pharmaceutical Vigilance administration is the way through which the processes for authorizing, Reguing, 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 2026

Volume 20 Issue 5

Drug Safety Update : Xylometazoline / Oxymetazoline; Increased Risk of Rebound Congestion, Rhinitis Medicamentosa, and Tachyphylaxis with Overuse

The regulatory authority in UK published the following drug Safety Update : Xylometazoline and oxymetazoline are sympathomimetic nasal decongestant sprays and drops used for the symptomatic relief of nasal and sinus congestion associated with the common cold, sinusitis, and allergic rhinitis in adults and children 6 years and above. They are also used for the treatment of flu symptoms in adults and children 12 years and above.
Xylometazoline is approved for use as a single active substance or in fixed-dose combinations with dexpanthenol and ipratropium bromide. Oxymetazoline is approved as a single active substance only.
Reports of rebound congestion, rhinitis medicamentosa, and tachyphylaxis — especially with prolonged or extended use — prompted a formal safety review by the MHRA. The review was assessed by the Cardiovascular, Respiratory, Renal and Allergy Expert Advisory Group (CDRRA EAG) and the Pharmacovigilance Expert Advisory Group (PEAG) of the Commission on Human Medicines (CHM).

Condition	Description
Rebound Congestion	A temporary response in which nasal passages become more congested after the medication wears off, typically occurring with use beyond the recommended duration.
Rhinitis Medicamentosa	The most serious of the three conditions. A chronic condition developing through prolonged use, characterised by severe nasal congestion with visible changes to the nasal mucosa and internal nasal structures. In severe, untreated cases, irreversible structural changes may require surgical intervention.
Tachyphylaxis	An acute, rapid decrease in response to the drug after repeated administration, leading to rapid-onset tolerance. Effects become apparent after more than 5 days of continuous use, causing users to increase frequency and/or duration to achieve relief.

Label Change

Following the safety review, the MHRA has recommended the following updates to the Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), and outer package labelling:
Maximum duration of use reduced from 7 days to 5 days in adults and children 12 years and above.
SmPC and PIL to be updated to highlight that these medicines are intended for short-term use only.
Repeated and/or prolonged use can increase the risk of side effects — to be explicitly stated.
Outer package labelling to be updated to emphasize the recommended duration of use.
Product information will be transitioning over the next few months.

Drug Safety Update : Xylometazoline / Oxymetazoline; Increased Risk of Rebound Congestion, Rhinitis Medicamentosa, and Tachyphylaxis with Overuse

Recommendations for Healthcare Professionals

- Rebound congestion, rhinitis medicamentosa, and tachyphylaxis through overuse are recognised side effects when these medicines are used beyond the maximum recommended duration.
- Patients may mistakenly interpret a rebound congestion effect as a continuation of the original congestion.
- Advise patients and caregivers that xylometazoline and oxymetazoline are for short-term use only — advise against use beyond 5 consecutive days.
- Advise patients not to exceed the daily recommended dose and to observe the minimum dosing interval stated in the product information.
- If nasal congestion persists, worsens, or does not improve after 5 days, alternative treatment may be required.
- Opportunistically review patients who may have become reliant on these products and advise them on how to gradually stop; abrupt discontinuation can worsen symptoms, but patients typically recover within 3 months with early recognition and treatment.
- In severe rhinitis medicamentosa, management may require a tailored treatment plan including gradual withdrawal, alternative therapies, and clinical follow-up.
- These medicines are contraindicated in patients taking other oral and nasal forms of sympathomimetic decongestants (e.g. pseudoephedrine, phenylephrine, ephedrine).
- Report suspected adverse drug reactions via the national pharmacovigilance system.

Key Messages for Patients

- Only use these medicines for a short time (no more than 5 consecutive days).
- Do not exceed the daily recommended dose or minimum dosing interval.
- If the nose becomes blocked again after the medicine wears off, or other symptoms appear (runny nose, sneezing, itching), this may be a rebound effect — talk to a healthcare professional.
- Do not use xylometazoline or oxymetazoline together or with other oral/nasal decongestants.
- Contact a doctor if symptoms worsen or do not improve after 5 days.

References

1. ***MHRA:*** *Click here*

Local Case Safety Report: Neurotoxicity after usage of colistimethate sodium

The regional pharmacovigilance center in Cairo received a case report involving a 45-year-old female patient with anuria and a history of recurrent urinary tract infections (UTIs) and cystitis. Her medical history was significant for a left nephrectomy performed 12 years prior due to left renal atrophy. Over the past six months, her UTIs persisted despite multiple courses of various antibiotics, prompting her physician to order a urine culture and prescribe intravenous colistimethate sodium. Following the administration of a single 9 million IU loading dose, the patient acutely developed severe neurotoxicity characterized by numbness in her lips, tongue, face, hands, and feet, alongside dyspnea and a sudden inability to stand or walk. This adverse drug reaction required an extended hospital stay; however, the patient fully recovered after the medication was permanently discontinued.

Background:

Colistimethate is indicated for the management of acute and chronic infections caused by susceptible strains of specific gram-negative bacilli, particularly infections associated with sensitive strains of Pseudomonas aeruginosa infection.

Parenteral colistimethate may be initiated in severe infections suspected to result from gram-negative organisms and may also be utilized for the treatment of infections caused by susceptible gram-negative pathogenic bacilli.

Mechanism of action

The initial interaction of colistin with the bacterial membrane is mediated by electrostatic attraction between the cationic polypeptide structure of colistin and the anionic lipopolysaccharides present in the outer membrane of Gram-negative bacteria. This interaction disrupts membrane integrity, increases cell envelope permeability, and results in leakage of intracellular contents, ultimately leading to bacterial cell death.

Alternative mechanisms have also been proposed, including intracellular activity whereby colistin may induce precipitation of ribosomes and other cytoplasmic constituents. Nevertheless, the precise mechanism of action has not been fully elucidated and remains incompletely understood.

Literature findings

According to a case report published in a PubMed-indexed journal, the most frequently reported adverse effects associated with colistin therapy are nephrotoxicity and neurotoxicity.

Neurological manifestations may include dizziness, muscular weakness, facial and peripheral paresthesia, visual impairment, vertigo, confusion, hallucinations, seizures, ataxia, partial hearing loss, and neuromuscular blockade.

In the reported case, the patient developed encephalopathy four days after initiation of colistin therapy. Clinical manifestations included drowsiness, confusion, rigors, finger twitching, and hallucinations. Colistin was considered the most probable causative agent, as the patient was not receiving any other medication known to induce neurotoxicity. In addition, the patient showed rapid clinical improvement following discontinuation of colistin treatment.

The neurotoxic effects of colistin are believed to result from non-competitive presynaptic neuromuscular blockade leading to inhibition of acetylcholine release. Evidence suggests that colistin-associated neurotoxicity is more closely related to the cumulative administered dose of colistimethate sodium rather than the daily or single dose, which may explain the delayed onset of symptoms after four days of therapy. Neurotoxicity has been reported more frequently in females and in patients with renal impairment or Myasthenia gravis.

Labelled information

According to the Summary of Product Characteristics (SmPC), this risk is addressed under the section "Special Warnings and Precautions for Use."

Local Case Safety Report: Neurotoxicity after usage of colistimethate sodium

Elevated serum concentrations of colistimethate sodium, which may occur due to overdose or failure to appropriately adjust the dose in patients with renal impairment, have been associated with neurotoxic reactions including facial paresthesia, muscle weakness, vertigo, slurred speech, vasomotor instability, visual disturbances, confusion, psychotic reactions, and apnea. Patients should be carefully monitored for signs of overdose, particularly perioral and peripheral paresthesia.

Renal impairment may increase the risk of apnea and neuromuscular blockade following administration of colistimethate sodium.

The concomitant administration of intravenous colistimethate sodium with agents known to possess nephrotoxic or neurotoxic potential should be approached with extreme caution. Concurrent use with other neurotoxic and/or nephrotoxic medicinal products, especially aminoglycosides such as Gentamicin, Amikacin, Netilmicin, and Tobramycin, should preferably be avoided.

Under the section "Effects on Ability to Drive and Use Machines," the SmPC indicates that parenteral administration of colistimethate sodium may result in neurotoxic effects such as dizziness, confusion, and visual disturbances. Patients should therefore be advised not to drive or operate machinery if such symptoms occur.

Regarding undesirable effects, neurological adverse events have been reported in up to 27% of patients with Cystic fibrosis receiving colistimethate sodium. These reactions are generally mild in severity and usually resolve during treatment or shortly after discontinuation.

Recommendations for Healthcare Professionals

Patient history should be reviewed carefully, as reduced renal function may increase the risk of apnoea and neuromuscular blockade following administration of colistimethate sodium.

The concomitant use of intravenous colistimethate sodium with other agents that possess nephrotoxic or neurotoxic potential should be undertaken with extreme caution.

Co-administration with other medicinal products known to have nephrotoxic and/or neurotoxic effects should generally be avoided. This includes aminoglycoside antibiotics such as gentamicin, amikacin, netilmicin, and tobramycin.

Colistin (administered as colistimethate sodium, CMS) is primarily eliminated via renal excretion. In patients with impaired renal function, maintaining efficacy while reducing nephrotoxicity requires individualized dose reduction, prolonged dosing intervals, and, where available, therapeutic drug monitoring.

Renal function parameters, including serum creatinine and estimated creatinine clearance, should be assessed at baseline and monitored frequently (ideally daily during the first week of treatment), with dose adjustments made as needed in response to changes in renal function.

References

1. **Colistimethate sodium SmPC:** (click here)
2. **EMA assessment report (Polymyxin-based products)** (click here)
3. **Colistin neurotoxicity case report** (click here)

EPVC Continues the Activities of the Be Vigilant Initiative 2026–2027

The Egyptian Drug Authority is pleased to welcome the Egyptian Health Authority (EHA) and Saudi German Hospital Alexandria as valued participants in the Be Vigilant Initiative – under the theme "Expand the Learning More…" Cohort 2.

This initiative is designed to support pharmacovigilance focal points across healthcare facilities and enhance the skills of users of the national database, particularly in managing and utilizing Vigiflow effectively.

EPVC is proud to continue the activities of the Be Vigilant Initiative through expanded collaboration, with a total of 6 focal points nominated from various governorates. This reflects the active participation and strong commitment of institutions to advancing pharmacovigilance through improving the efficiency and consistency of adverse drug reaction (ADR) collection and reporting.

As part of the initiative, 7 lectures were delivered across 5 webinars, providing a total of 15 training hours.

Title: PVGA conducts an orientation session about National PV system at MSA university

The Pharmaceutical Vigilance General Administration (PVGA) successfully conducted an interactive seminar for 110 MSA University students and teaching assistants, led by Dr. Mahmoud Osama, and Dr. Mai Gamal.

The event provided an in-depth exploration of the pharmacovigilance landscape, highlighting the EDA's national role in ensuring patient safety and the critical responsibilities of future pharmacists.

This engagement underscores our commitment to fostering academic collaboration and equipping the next generation of healthcare professionals with essential regulatory insights."

EPVC Tips

On Pharmacovigilance

"Right medicine, right patient, right dose, right duration."

Overuse of medicines can increase the risk of adverse drug reactions, drug resistance, dependence, and treatment failure. In pharmacovigilance practice, healthcare professionals should:
Use medicines only when clinically indicated.
Follow the recommended dose and duration.
Avoid unnecessary antibiotics, painkillers, and supplements.
Educate patients not to self-medicate or share medicines.
Monitor repeated prescriptions for signs of misuse or duplication.
Report suspected adverse reactions or medication overuse issues

By working together, we can ensure medications remain safe and effective tools for improving health
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.

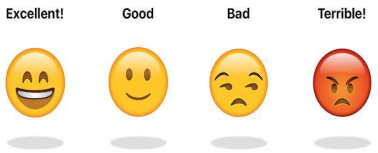
What is the Egyptian Pharmaceutical Vigilance Center?

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 الصيدلية)