



هيئة الدواء المصرية

IN THIS ISSUE

Safety Notification : Updated Prescribing Controls and Rising Risks from Isotretinoin Misuse 1-2

Local Case Safety Report: Reported Posterior Reversible Encephalopathy Syndrome in Two Pediatric Oncology Patients Receiving Cyclophosphamide Containing Chemotherapy 3-4

EPVC NEWS 5-6

EPVC Tips 7

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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

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Safety Notification : Updated Prescribing Controls and Rising Risks from Isotretinoin Misuse

The regulatory authority in France and UK recently highlight a dual focus: optimising safe access to treatment while addressing emerging public health risks linked to misuse.

Isotretinoin, an oral retinoid derived from vitamin A, remains one of the most effective treatments for severe acne unresponsive to conventional therapies. However, its use is tightly regulated due to serious and well-documented risks, including teratogenicity, psychiatric adverse effects, and systemic toxicity.

Evolving Prescribing Framework

Following a comprehensive safety review by the Commission on Human Medicines, the MHRA has updated isotretinoin prescribing requirements effective 22 January 2026. The previous requirement for a second prescriber's agreement in patients under 18 years has been removed after evidence showed it contributed to treatment delays with limited additional clinical benefit.

This change is supported by strengthened risk minimization measures, including:

- A revised Acknowledgement of Risk (AoR) form
- A mandatory patient information video prior to treatment initiation
- A structured clinical audit program led by the British Association of Dermatologists

Despite this streamlining, all core safety requirements remain unchanged. Isotretinoin must only be prescribed for severe acne, and the Pregnancy Prevention program (PPP) continues to be mandatory. This includes confirmed negative pregnancy tests, effective contraception, and limiting prescriptions to a maximum of 30 days. Ongoing monitoring for psychiatric symptoms, liver function abnormalities, lipid changes, and other adverse effects is essential throughout treatment and after discontinuation.

Growing Concern: Misuse Driven by Social Media

Alongside these regulatory updates, the ANSM has issued a safety alert (March 2026) regarding the misuse of isotretinoin for aesthetic purposes, followed by misinformation circulating on social media platforms. Claims that isotretinoin can “slim the nose” or enhance general appearance are not evidence-based and fall entirely outside its authorised indications.

Such misuse is particularly concerning given the drug's risk profile. Unsupervised use exposes individuals to potentially severe consequences, including:

- Major fetal malformations and pregnancy loss due to teratogenicity
- Psychiatric effects, including depression and suicidal ideation
- Hepatotoxicity and hyperlipidaemia
- Ocular complications such as dry eye syndrome
- Musculoskeletal symptoms and significant skin irritation



Safety Notification : Updated Prescribing Controls and Rising Risks from Isotretinoin Misuse

Importantly, these risks may occur even at low doses and can persist after treatment cessation. Additionally, obtaining isotretinoin without a prescription—particularly via online sources—is illegal and bypasses essential medical safeguards.

Clinical Implications

Healthcare professionals play a critical role in ensuring safe use of isotretinoin. This includes:

- Restricting prescribing strictly to licensed indications
- Ensuring full compliance with all risk minimization measures, particularly the Pregnancy Prevention program
- Providing thorough patient counselling using updated educational tools
- Actively addressing and correcting social media misinformation
- Monitoring all patients regularly, including mental health assessment and laboratory investigations
- Encouraging prompt reporting of suspected adverse drug reactions

Key Message

Recent actions by regulators reflect a consistent and clear position:

- Isotretinoin access may be streamlined, but its safe use depends on strict adherence to prescribing controls and active prevention of misuse.
- Use outside approved indications—particularly for cosmetic purposes—is inappropriate, ineffective, and potentially dangerous.

References

1. **MHRA:** [Click here](#)
2. **ANSM :** [Click here](#)

Local Case Safety Report: Reported Posterior Reversible Encephalopathy Syndrome in Two Pediatric Oncology Patients Receiving Cyclophosphamide Containing Chemotherapy

EPVC received two serious case reports concerning pediatric oncology patients who developed neurological manifestations following chemotherapy administration. Upon follow-up, both patients were confirmed to have Posterior Reversible Encephalopathy Syndrome (PRES).

The cases involved a 4-year-old male child and a 4.5-year-old female child. The first patient had renal cancer, while the second patient had neuroblastoma. No relevant medical history or previous medication history was reported for either patient. Both patients received intravenous cyclophosphamide in combination with doxorubicin.

In the first case, the reaction occurred one day after receiving cyclophosphamide at a dose of 352.5 mg on days 1, 2, and 3. In the second case, the reaction occurred 16 days after the last cyclophosphamide dose of 1470 mg. The patients presented with signs of toxicity and neurological manifestations as follows: The first patient developed transient loss of vision and retinal detachment, followed by ascites. While the second patient developed fits/seizures associated with elevated blood pressure, reaching 180/100 mmHg.

Background:

Posterior Reversible Encephalopathy Syndrome (PRES): PRES is a neurovascular syndrome characterized by acute or subacute neurological manifestations that typically emerge within hours to several days such as seizures, encephalopathy, headache, altered mental status, nausea/vomiting, and visual disturbances, including blurred vision or transient blindness. PRES is often associated with acute hypertension, renal impairment, cytotoxic or immunosuppressive therapy, sepsis, autoimmune disease, transplantation, and malignancy.

PRES is multifactorial, and depends on a high index of clinical suspicion and should be considered in any patient receiving chemotherapy who develops: new onset seizure, severe headache, visual disturbance, altered consciousness, confusion, persistent vomiting, or acute hypertension.

Clinical diagnosis and follow-up assessment remain important in real-world reporting. So; early recognition and proactive monitoring are keys of controlling.

PRES with Patient Receiving Chemotherapy Therapy

In oncology patients, PRES may occur in the presence of several overlapping risk factors, including chemotherapy exposure, immunosuppressive therapy, hypertension, renal impairment, infection or sepsis, fluid overload, tumor related metabolic disturbance, and treatment related electrolyte abnormalities.

Method of administration:

IV as bolus injection or infusion very slowly between 30 minutes and 2 hours.

To reduce the risk of ADR that appear to be administration rate-dependent (e.g., facial swelling, headache, nasal congestion, scalp burning).

- Mechanism of action:

Cyclophosphamide is an alkylating prodrug that is activated in the liver and works by cross-linking DNA, thereby inhibiting cancer cell replication and causing cell death.

Cyclophosphamide has a biologically plausible association with PRES. As a cytotoxic alkylating agent, it may contribute to endothelial dysfunction and blood-brain barrier disruption, especially in the presence of hypertension, renal impairment, fluid/electrolyte imbalance, or other chemotherapy-related stressors.

Labeled indication and doses

Cyclophosphamide is used in Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma, multiple myeloma, leukemias, mycosis fungoides, neuroblastoma, adenocarcinoma of ovary, retinoblastoma, breast carcinoma.

The dose, duration and treatment intervals are based on the respective therapeutic indication and combination treatment regimen.

When cyclophosphamide is included in combined cytotoxic regimens, it may be necessary to reduce the dose of cyclophosphamide as well as that of the other drugs.

Neuroblastoma: Dependent on the stage of the disease and the patient's age, cyclophosphamide is used in various chemotherapy protocols. The "OPEC protocol" for advanced neuroblastoma: 600 mg/m² of BSA cyclophosphamide IV on day 1 in combination with vincristine, cisplatin and teniposide; repeat every 3 weeks.

Renal Tumor: Cyclophosphamide may be used in selected pediatric renal tumors as part of multi-agent chemotherapy regimens. Dosing should be determined according to the specific tumor type, risk stratification, treatment protocol, and patient-related clinical factors.

Contraindications & Warnings

Cyclophosphamide should not be used in patients with known hypersensitivity to cyclophosphamide, its metabolites or to any of the excipients, severe impairment of bone marrow function, inflammation of the bladder (cystitis), urinary obstruction, florid infections.

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any of the excipients, severe impairment of bone marrow function, inflammation of the bladder (cystitis), urinary obstruction, florid infections.

Special warnings for cyclophosphamide that should be used with caution and close monitoring in next conditions: older patients, patients who have previously undergone radiation treatment, patients with weakened immune systems, diabetes mellitus, chronic liver or kidney diseases and preexisting cardiac disease and patients with acute porphyria.

Labeled information:

- Nervous system disorders: Peripheral neuropathy, Polyneuropathy, Neuralgia, Dizziness, Seizures, Encephalopathy, Neurotoxicity, Reversible posterior leukoencephalopathy syndrome, Myelopathy,
- Eye disorders: Blurred vision, Visual disturbances, Conjunctivitis, Eye edema.
- Vascular disorders: Low blood pressure, Hypertension, Hypotension.
- Gastrointestinal disorders: Stomatitis, Acute pancreatitis, Ascites.
- Hepatobiliary disorders: Veno-occlusive liver disease, Hepatic encephalopathy.

Prevention and Early Detection

Clinical diagnosis and follow-up assessment remain important components of real-world pharmacovigilance reporting, early recognition and proactive monitoring are key and should include:

Monitoring blood pressure before, during, and after chemotherapy cycles.

Assessing renal function, electrolytes, fluid balance, and signs of infection or tumor lysis.

Performing neurological evaluation and brain MRI when PRES is suspected.

Reviewing concomitant medicines that may increase blood pressure or contribute to neurotoxicity.

Conclusion

These cases highlight an uncommon but clinically significant adverse reaction following cyclophosphamide-containing chemotherapy, which may contribute to the development of Posterior Reversible Encephalopathy Syndrome (PRES) through biologically plausible mechanisms.

The causality linked to the temporal association, clinical presentation, and improvement after discontinuation of the suspected medicines support a possible association.

Recommendations for Healthcare Professionals:

Maintain clinical suspicion of PRES: Consider PRES in adult/pediatric oncology patients receiving cyclophosphamide-containing chemotherapy who develop visual symptoms, seizures, altered mental status, persistent vomiting, headache, or hypertension.

Perform baseline assessment before chemotherapy: before initiation assess neurological status, visual complaints, blood pressure, renal and liver function, electrolytes, and hydration status.

Monitor closely during and after chemotherapy cycles: Pay attention to any uncommon or early reactions while using with chemotherapy agents with PRES e.g. seizures, visual disturbance, severe headache, persistent vomiting, irritability, confusion, or altered consciousness.

Act promptly when PRES is suspected: If PRES is suspected, arrange urgent multidisciplinary assessment and perform brain MRI where feasible, as CT may be normal in some cases.

Avoid rechallenge: Do not re introduce the agent again unless the expected oncological benefit clearly outweighs the risk and enhanced monitoring/preventive measures are implemented.

Report and document suspected ADRs: Report suspected ADRs to the pharmacovigilance authority, including chemotherapy doses, body surface area, protocol, cycle number, batch number, infusion details, blood pressure trend, imaging findings, laboratory results, management, de-challenge /rechallenge information, and outcome.

Review chemotherapy continuation carefully: Reassess the suspected chemotherapy regimen through a multidisciplinary benefit-risk evaluation. Withholding, delaying, reducing, or modifying chemotherapy may be considered according to the severity of PRES, patient recovery, cancer status, recurrence risk, and availability of alternative treatment options.

References

1. **PRESS diagnosis and management BMJ** ([click here](#))
2. **Pediatric Renal Tumors** ([click here](#))
3. **Cyclophosphamide SmPC EDA** ([click here](#))
4. **Case Report NIH** ([click here](#)).
5. **Case Report Science Direct** ([click here](#))

Agile Mindset for Growth Initiative 2026–2027

The Egyptian Drug Authority is pleased to announce an official visit to AASTMT Alamein Campus under the “Agile Mindset for Growth Initiative 2026–2027,” upon the kind invitation of Dr. Evan Ibrahim, Dean of the College of Pharmacy.



This initiative aims to integrate university medical students into the field of pharmacovigilance by enhancing their capabilities and equipping them with the essential skills needed to support drug safety and achieve its primary goal: ensuring patient safety.

During the visit, two engaging lectures were delivered covering “The Pharmacovigilance Landscape in Egypt and Globally” and “Reporting Cycle and Channels.” The event also featured an interactive workshop utilizing a game-based learning approach, which resulted in strong engagement from attendees.

The event was attended by 134 participants, including academic staff, teaching assistants, and students reflecting a growing academic interest in promoting and strengthening pharmacovigilance awareness among future healthcare professionals.



Vigitest Competition 2026 – Round 1 with Live Pharmacovigilance Challenge winners

We appreciate your attendance and engagement in Round 1 of VigiTest 2026, we reached 45 participants in round 1. Thank you for participating, and please join us in congratulating our top 3 winners on their achievement:

Name	Title	Affiliation
Noura Gad	Pharmacy student	6 th October University
Manar Hassan	Clinical Pharmacist	Educational Mataria hospital
Rogy Reda	Ass. prof of pharmaceutical organic chemistry	faculty of pharmacy port said university



Vigitest Competition 2026 – Round 2 with Live Pharmacovigilance Challenge

Following the successful launch of Vigitest in 2026 round 1, where participants competed in interactive live Game; we are excited to announce the Round 2 of the Vigitest competition in a new, dynamic live format for 2026.

Stay tuned for rapid-fire rounds and simulations that test your PV expertise in real-time.

How to Join Vigitest 2026

Register your participation by submitting your name through the Google Form linked below.

Scan the QR code or tap the link below, follow the instruction and answer the questions.

Or copy the link:

https://docs.google.com/forms/d/e/1FAIpQLSetBbvH_U8JDZnJZzDIHm2383ZgJVgzwqrqOcjSh-AiEOBVYO/viewform?usp=dialog

Once registered, you will receive an invitation email one day before the competition, including:

Exact date and time of your competition round

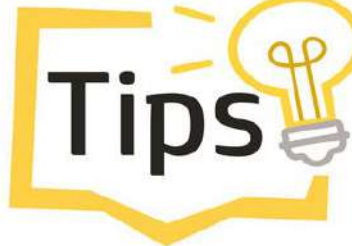
Instructions on accessing the live platform

This is your chance to showcase your PV skills, test your knowledge against peers, and continue the legacy of Vigitest in a live, engaging environment.

Don't miss the opportunity to be part of the Vigitest Game 2026 – where knowledge meets action!



EPVC



On Pharmacovigilance

Drug Misuse is a Shared Responsibility

Medication misuse—whether intentional or unintentional—remains a growing public health concern. It can lead to treatment failure, adverse drug events, dependency, and even death. Both healthcare professionals and the public play critical roles in minimizing these risks.

For Healthcare Professionals:

- Prescribe thoughtfully: Evaluate patient history, potential for misuse, and alternative therapies before prescribing.
- Communicate clearly: Provide explicit instructions on dosage, duration, and potential side effects.
- Monitor regularly: Follow up with patients, especially when prescribing high-risk medications such as opioids, sedatives, or stimulants.
- Promote safe storage and disposal: Encourage patients to keep medications secure and dispose of unused drugs properly.
- Stay informed: Keep up with guidelines on safe prescribing and emerging patterns of misuse.

For the Public:

- Follow directions exactly: Never take more than prescribed or use someone else's medication.
- Ask questions: Understand why the medication is prescribed and how to take it safely.
- Avoid self-medication: Especially with antibiotics, painkillers, or sedatives.
- Store safely: Keep medications out of reach of children and others.
- Preventing drug misuse starts with awareness, communication, and responsible practices.

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.

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 .

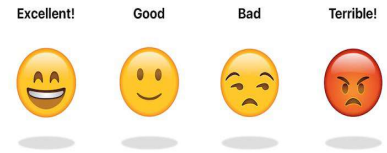
EPVC monitors the safety of all types of pharmaceutical products, including human medicines, biological products, supplements, cosmetics, veterinary medicines, medical devices, Biocides and pesticides

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: [\(click Here\)](#)



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