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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 Information : Risk of hypophosphatemia and bone disorder risk with administration injectable iron-containing medicines

Introduction

The regulatory Authority in Europe (EMA) has released a class-wide safety notice concerning injectable iron-containing medicines and the risk of hypophosphatemia and related bone disorders. Given the wide use of injectable iron products in Egypt for iron deficiency anemia, this review is relevant to monitor this risk as it develops. This action follows previous warnings from the U.S. Food and Drug Administration (FDA) in 2019/2020, and the European Medicines Agency (EMA) in 2020, regarding the risk of hypophosphatemia specifically with ferric carboxymaltose. The current PRAC review was initiated due to concerns about the effectiveness of existing risk-minimization measures. Notably, the review extends to all injectable iron-containing medicines, highlighting the importance of continued pharmacovigilance, appropriate monitoring, and reporting of suspected adverse reactions.

Background

Injectable iron-containing medicines are used to treat iron deficiency and iron deficiency anemia in patients who cannot tolerate or do not respond adequately to oral iron. The PRAC has started a review of the risk of hypophosphatemia (low blood phosphate levels) and related bone disorders associated with this class of medicines, along with the effectiveness of existing risk-minimization measures already in place.



This type of procedure: PRAC referral (safety review of a class of medicines) — not yet a final regulatory decision.

Scope of the review: the risk of hypophosphatasemia and associated bone disorders across injectable iron-containing medicines as a class.

What the Committee will assess: whether these risks affect the overall benefit-risk balance of the medicines, and whether changes to their marketing authorizations are needed.

Recommendation to Healthcare professionals

Be aware of the risk: Injectable iron-containing medicines have been associated with hypophosphatemia (low blood phosphate levels), which may lead to bone disorders, particularly with repeated or prolonged treatment.

Monitor at-risk patients: Consider monitoring serum phosphate levels in patients receiving repeated courses or those at increased risk, and investigate persistent or unexplained bone pain or other relevant symptoms.

Report suspected cases: Healthcare professionals are encouraged to report suspected hypophosphatemia and related bone disorders associated with injectable iron medicines through the national pharmacovigilance reporting system. The EMA/PRAC review is ongoing and is not yet a final regulatory decision.

References

1. ***EMA:*** *Click here*

DHPC : Desogestrel- and etonogestrel-containing medicines: risk of meningioma and new measures to minimize this risk

Background

The Egyptian Drug Authority (EDA) is alerting healthcare professionals about a slightly increased risk of meningioma associated with the long-term progestogens use including desogestrel- and etonogestrel-containing medicines. The risk has been observed particularly during current long-term use, defined as one year or longer. Desogestrel and etonogestrel are progestogens used primarily for contraception. Desogestrel-containing medicines are available as oral tablets, while etonogestrel-containing medicines are available as contraceptive implants and, in combination with ethinylestradiol, as vaginal rings. Meningiomas are tumors arising from the tissue layers surrounding the brain and spinal cord. They are usually benign and slow-growing; however, depending on their size and location, they may cause serious neurological complications. Although the risk of meningioma is increased with the use of these medicines, the overall likelihood remains very low, with approximately one additional case of meningioma estimated per 67,300 women treated with desogestrel. Meningioma risk is already established for other progestogens (cyproterone, nomegestrol, medroxyprogesterone, and chlormadinone). This review expands existing safety measures to desogestrel and etonogestrel, rather than identifying a novel risk."
The EDA has issued a Direct Healthcare Professional Communication (DHPC) regarding this safety concern and the measures required to minimize the associated risk. Healthcare professionals are advised that the use of desogestrel- or etonogestrel-containing medicines is contraindicated in women with a current or previous history of meningioma.

Risk Factors and Contributing Considerations:

The risk of meningioma may be higher in women who have previously used other progestogens known to be associated with an increased risk of meningioma. These include cyproterone, nomegestrol, medroxyprogesterone, and chlormadinone. Therefore, previous exposure to these medicines should be considered when assessing patients before initiating treatment with desogestrel- or etonogestrel-containing medicines.
The potential association with meningioma is particularly relevant during long-term exposure, highlighting the importance of reviewing the patient's medical history and considering previous progestogen exposure when selecting contraceptive treatment.

Current Situation

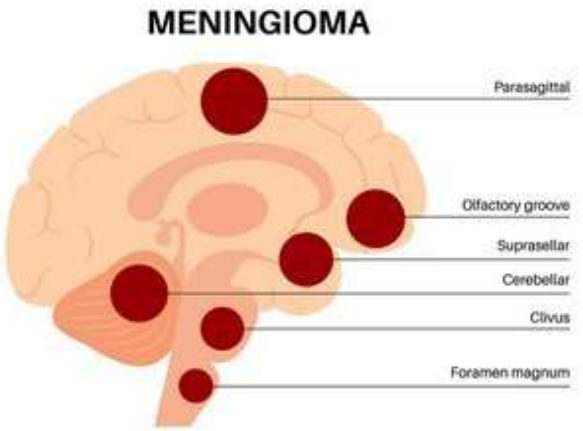
The EDA continues to monitor available safety information concerning desogestrel- and etonogestrel-containing medicines and their potential association with meningioma. The identified risk has led to strengthened recommendations intended to support the appropriate use of these medicines and minimise potential harm.
Healthcare professionals should remain vigilant for signs and symptoms suggestive of meningioma in women receiving these medicines. If a patient is diagnosed with meningioma while receiving desogestrel or etonogestrel, treatment should be discontinued

Safety Information : Desogestrel- and etonogestrel-containing medicines: risk of meningioma and new measures to minimize this risk

Measures to Minimize the Risk

Healthcare professionals should consider the following measures when prescribing or dispensing desogestrel- or etonogestrel-containing medicines:

- Avoid use in women with a current or previous history of meningioma.
- Review the patient's medical history before initiating treatment.
- Consider previous exposure to progestogens associated with an increased risk of meningioma.
- Monitor women receiving these medicines for relevant signs and symptoms of meningioma which include changes in vision, hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss , seizures or weakness in the extremities
- Discontinue treatment if meningioma is diagnosed.
- Ensure that patients are appropriately counselled regarding the safety information and the importance of reporting relevant symptoms.



- Report any suspected adverse reactions associated with desogestrel- or etonogestrel-containing medicines to the General Administration for Pharmaceutical Vigilance (GAPV) at the EDA.

Product Information Update

- The relevant Summary of Product Characteristics (SmPC) has been updated to include information regarding meningioma. Under Warnings and Precautions, meningioma is identified as a potential risk associated with long-term administration of progestins, and desogestrel- or etonogestrel-containing medicines should be discontinued if meningioma is diagnosed. Meningioma has also been included under Adverse Reactions. In addition, caution is advised when recommending medroxyprogesterone to patients with a history of meningioma.

Key Message

- Healthcare professionals are encouraged to remain aware of the very low but increased risk of meningioma associated with long-term use of desogestrel- and etonogestrel-containing medicines. Appropriate patient selection, consideration of previous progestogen exposure, monitoring for relevant symptoms, and discontinuation of treatment when meningioma is diagnosed are important measures to minimize the potential risk and support the safe use of these medicines.

References

1. ***EMA:*** *Click here*
2. ***BfArM (Germany) :*** *Click here*
3. ***DHPC:*** *Click here*

Local Case Safety Report: Increased Blood Pressure Following Chlorpheniramine/ Dexamethasone Use

This case highlights the importance of taking the patient's medical history before prescribing and strictly adhering to the recommended dose stated in the product's Summary of Product Characteristics (SPC).

Cairo Regional Pharmacovigilance Center received an Individual Case Safety Report concerning a 60-year-old female patient, weighing 60 kg, with a history of chronic hypertension and receiving antihypertensive treatment chronically, was treated for cough. Upon physician prescription, she started (chlorpheniramine 2 mg/5 mL and dexamethasone 0.5 mg/5 mL) syrup orally with dose of 10 ml every 8 hours (twice the recommended dose as stated in the drug SPC) for cough. Which indicates off label dosing . Following treatment on the same day, the patient experienced increased blood pressure. The patient discontinued the suspect drug on 4 February 2026, following which the increased blood pressure resolved on the same day, indicating a positive dechallenge. According to the WHO-UMC causality assessment scale, this case is classified as Probable due to the positive dechallenge.

It's important to mention that this is not the first case for such issue, EPVC has received 8 cases concerning hypertension with the use of cold medications

Background:

Pharmacological Actions

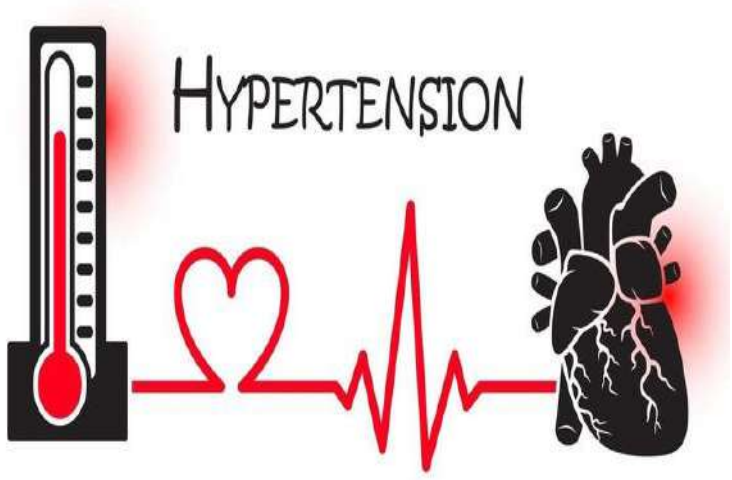
Dexamethasone, Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli. At equipotent anti-inflammatory doses, dexamethasone almost completely lacks the sodium retaining property of hydrocortisone and closely related derivatives of hydrocortisone. However, glucocorticoids can still elevate blood pressure through non-renal mechanisms."

Chlorpheniramine antagonizes competitively the effects of histamine on H1-receptors and also has weak antimuscarinic and moderate ant serotonin and local anesthetic actions. It penetrates the brain and causes stimulation or sedation in animals.

Indications (1):

- Perennial and seasonal allergic rhinitis
- Vasomotor rhinitis
- Allergic conjunctivitis due to inhalant allergens and foods
- Mild, uncomplicated allergic skin manifestations of urticaria

According to the drug's SPC, it should be used with caution in patients with hypertension.



Dose

This medicine is only prescribed by the physician The dose and duration of use should be determined by the treating physician

Adults: One teaspoonful (5 ml), 3 times daily.

Children (6-12 years): 1/2 teaspoonful (2.5 ml) 3 times daily.

Knowing that the dose ranges of dexamethasone for adults is 0.75 mg to 9 mg per day and for children is 0.02 mg to 0.3 mg/kg/day (0.6 mg to 9 mg /body surface area m2 /day)

Two Medication-Safety Risks Identified in this case

1- The Importance of Medication Reconciliation and Medical History Review

- The patient had a history of chronic hypertension and was receiving antihypertensive treatment. However, her medical history and current medications were not adequately assessed before prescribing the cough medication.
- Had the physician asked about the patient's medical history, the patient could have been appropriately advised to monitor her blood pressure more closely during treatment.

2- Administration of a Dose Higher Than the Recommended Dose

The patient administered the syrup at 10 mL every 8 hours, while the SPC-recommended dose is 5 mL (2mg) every 8 hours. Therefore, the patient administered twice the recommended dose.

This highlights the importance of ensuring that patients clearly understand the prescribed dose, frequency, and method of administration, particularly when using liquid formulations where dosing errors can occur easily.

Recommendations for Healthcare Professionals:

To minimize the risk of medication-related harm in patients receiving cough and antiallergic medications, healthcare professionals are encouraged to:

1. Conduct a Comprehensive Medical History and Medication Reconciliation

Before prescribing or recommending any medication, actively assess the patient's medical history and current medications, with particular attention to chronic conditions such as hypertension and cardiovascular disease.

2. Assess the Benefit–Risk Profile for the Individual Patient

Consider the patient's underlying conditions, concomitant medications, and relevant precautions before selecting a cough or antiallergic preparation. The presence of hypertension should prompt careful consideration of the appropriateness of treatment and the need for closer monitoring.

3. Refer to the Current Approved Product Information

Healthcare professionals should consult the current Summary of Product Characteristics (SPC) for the approved indication, recommended dose, contraindications, warnings, and precautions. In this case, the SPC recommends caution in patients with hypertension.

4. Educate and Counsel Patients

Patients should be clearly informed about the correct dose and dosing frequency and advised not to exceed the recommended dose. Patients with hypertension should also be informed about the importance of monitoring their blood pressure and reporting any significant or unexpected changes.

5. Monitor Patients at Increased Risk

Patients with pre-existing hypertension or other relevant cardiovascular risk factors may require closer clinical monitoring during treatment, particularly when the prescribed medicine carries warnings or precautions related to blood pressure.

Pharmacovigilance Take-Home Message

Know the patient. Reconcile the medications. Check the SPC. Verify the dose. Counsel the patient. Monitor when needed. Report suspected safety events.

References

1. **Drug SPC:** (click here)
2. **Dexamethasone (systemic): Drug information:** (click here)

EPVC Participates in the Third Libyan International Conference of Pharmacy

Advancing the Conversation on Digital Pharmacovigilance

The Egyptian Pharmacovigilance Center (EPVC) participated in the Third Libyan International Conference of Pharmacy, contributing to the professional discussions and knowledge exchange among pharmaceutical, healthcare, and pharmacovigilance professionals from across the region. The conference provided an important platform for discussing recent developments in pharmacy and pharmacovigilance and exploring emerging opportunities to strengthen medicine safety through innovation, digital transformation, and collaboration. As part of EPVC's participation, a presentation entitled "Digital Transformation & Digital PV" was delivered, focusing on the increasing role of digital technologies and Artificial Intelligence (AI) in transforming pharmacovigilance practices. The presentation highlighted the potential of digital solutions and AI to support the analysis and management of large volumes of safety information, facilitate pattern recognition and signal detection, improve the efficiency of pharmacovigilance processes, and contribute to more proactive and data-driven approaches to medicine safety. The conference also provided an opportunity to share professional perspectives and experiences, exchange knowledge with regional colleagues, and discuss the evolving landscape of pharmacovigilance. Such interactions contribute to strengthening regional cooperation, promoting the exchange of best practices, and supporting the continuous development of pharmacovigilance systems. EPVC's contribution was formally recognized by the conference organizers through a Certificate of Appreciation and a commemorative Shield, acknowledging the valuable contribution and active participation in the conference. This recognition highlights the value of EPVC's engagement in regional professional activities and reflects its continued commitment to advancing pharmacovigilance through innovation, knowledge sharing, digital transformation, and collaboration. Overall, EPVC's participation in the Third Libyan International Conference of Pharmacy represented a valuable opportunity to promote professional exchange and contribute to the regional dialogue on Digital Transformation and Digital Pharmacovigilance, reinforcing the importance of embracing emerging technologies and strengthening regional cooperation to support the future of pharmacovigilance and the safer use of medicines.





EPVC Tips On Pharmacovigilance

Think Safety at Every Step

* Safe medicine use starts with careful attention to every step of the treatment process. Before prescribing or dispensing a medicine:
* Know the patient and consider relevant medical history, including previous conditions and treatments.
* Reconcile the medications to identify previous or concomitant medicines that may affect treatment decisions.
* Check the Summary of Product Characteristics (SPC) for the latest safety information, contraindications, warnings, precautions, and recommendations.
* Verify the dose and route of administration to ensure the medicine is used correctly.
* Counsel the patient about important precautions, possible adverse reactions, and when to seek medical advice.
* Monitor when needed, particularly when treatment requires follow-up or when specific risks have been identified.

Finally, report any suspected adverse drug reactions or other safety events to support continuous pharmacovigilance and help improve the safe use of medicines. before using medicines if you have kidney problems or take several medicines.

Your medicine should help you—not harm you.

You can report any ADR on:
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)

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Reporting link: (click Here)