Direct Healthcare Professional Communication

August 2025

Medroxyprogesterone acetate Risk of meningioma and measures to minimize this risk

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance (PVGA) at the Egyptian drug authority (EDA) would like to inform you **about Risk of meningioma and measures to minimize this risk**

Summary

- There is an increased risk of developing meningioma with high doses of medroxyprogesterone acetate (injectable formulations), primarily after prolonged use (several years).
- For contraception or non-oncological indications:
  - Medicines containing high doses of medroxyprogesterone acetate are contraindicated in patients with meningioma or a history of meningioma.
  - If meningioma is diagnosed in a patient treated with high doses of medroxyprogesterone acetate, treatment must be stopped.
- Patients treated with high doses of medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma in accordance with clinical practice.

Background on the safety concern

- Medroxyprogesterone acetate Suspension for Injection is indicated for contraception.
- Meningioma is a rare, most frequently benign tumour that forms from the meninges. Clinical signs and symptoms of meningioma may be non-specific and 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. While meningiomas are usually benign, their location may lead to serious consequences and may require surgery.
- Based on results from a French epidemiological case-control study, an association between medroxyprogesterone acetate and meningioma has been observed. This study was based on data from the French National health data system (SNDS – Système National des Données de Santé) and included a population of 18, 061 women who had intracranial surgery for meningioma. Each case was matched to five controls per year of birth and area of residence (90, 305 controls).

- The exposure to medroxyprogesterone acetate 150 mg/3ml injectable was compared between women who had intracranial surgery for meningioma and women without meningioma. Analyses showed an excess risk of meningioma with the use of medroxyprogesterone acetate 150 mg/3 ml (9/18,061 cases (0.05%) vs. 11/90,305 controls (0.01%), odds ratio (OR) 5.55 (95% CI 2.27 to 13.56)).
- This excess risk seems to be driven by prolonged use (≥3 years) of medroxyprogesterone acetate 150 mg/3 ml. Although the relative risk of meningioma is significantly increased with the use of high dose medroxyprogesterone acetate, the absolute risks are very small. No new safety concern regarding a risk of meningioma associated with the use of low dose.

- The product information for all relevant medroxyprogesterone acetate containing medicines will be updated accordingly to include the following regarding Meningioma risk:

Summary of Product Characteristics

- Warnings and precautions

  Neurologic Meningioma Meningiomas have been reported following long-term administration of progestins, including medroxyprogesterone acetate (MPA). MPA should be discontinued if a meningioma is diagnosed. Caution is advised when recommending medroxyprogesterone to patients with a history of meningioma.

- Adverse reactions: Meningioma

Reference

EMA:https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-medroxyprogesterone-containing-medicines-risk-meningioma-measures-minimise-risk_en.pdf

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://vigiflow-eforms.who-umc.org/eg/med
QR Code:

PO Box: 11451

Hotline: 15301