SAFETY ALERT

DRAP SAFTEY ALERT NO. 59

Risk of meningioma with Medroxyprogesterone Acetate.

Date: 1st of July, 2025.

Target Audience.

- Provincial Health Departments/Provincial PV Centres/Healthcare Commissions;
- Manufacturers and importers of Medroxyprogesterone Acetate; and
- Healthcare Professionals.

Background.

The Pharmacovigilance Risk Assessment Expert Committee (PRAC) of the European Medicines Agency (EMA) in its meeting of September 2024, recommended measures to minimise the risk of meningioma, a type of brain tumour, with medicines containing medroxyprogesterone acetate (MPA). The committee's recommendations followed a review of data from epidemiological studies, case studies from the medical literature and cases reported in the pharmacovigilance database of the European Union. These data show an increased risk of meningioma in people taking high doses of medroxyprogesterone acetate (injectables and ≥100 mg tablets) for several years. Although the relative risk of meningioma is significantly increased with the use of high-dose medroxyprogesterone acetate, the absolute risk is very small. The PRAC recommended that, in patients who have a meningioma or have had one in the past, medicines containing high-dose medroxyprogesterone acetate must not be used, unless medroxyprogesterone acetate is needed for the treatment of an oncological indication. The PRAC also recommended that patients taking high doses of medroxyprogesterone should be monitored for symptoms of meningioma, which can include vision change, hearing loss or ringing in ears, loss of smell, headaches, memory loss, seizures and weakness in arms and legs.

Likewise, in its safety review reports issued through Infowatch (October 2024 issue), Health Canada informed that warnings and precautions and patient medication information sections of the Canadian product monographs of medicine containing medroxyprogesterone acetate have been updated with the risk of meningioma. It was also informed that meningiomas have been reported following long-term administration of progestins, including medroxyprogesterone acetate (MPA), and it should be discontinued if a meningioma is diagnosed. Caution is advised when recommending medroxyprogesterone to patients with a history of meningioma.

Meningiomas are tumours of the tissue layer surrounding the brain and spinal cord. Usually, they are benign and grow slowly, but, depending on the size or location, can cause serious problems.

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Action in Pakistan.

The case was discussed in the 5th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC) held on 2nd of Janauary, 2025 which decided as per Rule 10 (1) (h) (iv) of Pharmacovigilance Rules, 2022, that registration holders should update the product information of medicine containing medroxyprogesterone acetate (MPA) by including information about the risk of "meningioma" in the warning and precaution section.

Therapeutic Good Affected.

Name: Medroxyprogesterone acetate (MPA) is a medicine which is used for gynaecological (including contraception and endometriosis) and oncological indications.

Advice for Healthcare Professionals.

Cases of meningioma (single and multiple) have been reported in patients treated with medroxyprogesterone acetate for a prolonged time (several years). Patients treated with medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma in accordance with clinical practice. In some cases, shrinkage of meningioma was observed after treatment discontinuation of depot medroxyprogesterone acetate. If a patient treated for a non-oncological indication is diagnosed with meningioma, medroxyprogesterone acetate must be stopped, as a precautionary measure. If a patient treated for an oncological indication is diagnosed with meningioma, the need for further treatment with medroxyprogesterone acetate should be carefully considered on a case-by-case basis, taking into account individual benefits and risks.

Advice for patients.

Don't use medroxyprogesterone acetate if you have meningioma or have ever been diagnosed with a meningioma (usually a benign tumour of the tissue surrounding the brain and spinal cord) unless you use it for cancer. Use of medroxyprogesterone acetate has been linked to the development of a usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma). The risk increases especially when you use it for a longer duration (several years). If you are diagnosed with meningioma, your doctor will reconsider your treatment with medroxyprogesterone acetate. If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

Guidelines for reporting Adverse Drug Reactions (ADRs).

Healthcare professionals and patients are requested to report any adverse drug reaction with Medroxyprogesterone Acetate and/or any other medicine to the National Pharmacovigilance Centre (NPC), Drug Regulatory Authority of Pakistan (DRAP) through the Med Vigilance E-Reporting System (E-forms) available on the DRAP website. Similarly, adverse events and adverse drug reactions can also be reported through the VigiMobile App, which can be downloaded by scanning the barcode available on the DRAP website.

References.

- Minutes of the 5th meeting of the Pharmacovigilance Risk Assessment Expert Committee (PRAEC), DRAP.
- PRAC recommendations on signals adopted at the 2-5 September 2024.
- Health Canada: Health Product InfoWatch: October 2024.