DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)

28-10-2026

Regulon® (desogestrel/ethinylestradiol): Risk of meningioma and measures to minimise the risk

Dear Healthcare Professional,

In agreement with the Saudi Food and Drug Authority (SFDA), Aja pharma would like to inform you of the following:

Summary

- **There is a small increased risk of meningioma associated with current, prolonged use (≥1 year) of desogestrel- or etonogestrel-containing medicinal products.**
- **Use of desogestrel or etonogestrel is contraindicated in women with a meningioma or a history of meningioma.**
- **Women treated with desogestrel or etonogestrel should be monitored for signs and symptoms of meningioma.**
- **If a woman is diagnosed with meningioma, desogestrel or etonogestrel must be discontinued.**
- **The risk may be higher with previous exposure to progestogens already known to be associated with an increased risk of meningioma (for example cyproterone, nomegestrol, medroxyprogesterone, and chlormadinone); this should be considered before initiating treatment with desogestrel or etonogestrel.**
- **Overall, about one additional case of meningioma is estimated to occur for every 67,300 women treated with desogestrel.**

Background on the safety concern

Desogestrel and etonogestrel, alone or in combination with ethinyl estradiol, are indicated for contraception and are available as oral tablets, vaginal ring or subcutaneous implant. Desogestrel is metabolised to etonogestrel.

Meningioma is a rare, mostly 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, they can have serious consequences depending on their location and may require surgery.

Based on results from a French epidemiological case-control study[1], an association between desogestrel 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 8,391 women who had intracranial surgery for meningioma. Each case was matched to 10 controls per year of birth and area of residence (83,910 controls). A small increased risk of intracranial meningioma was observed with current, prolonged use (≥1 year) of desogestrel 75 micrograms (odds ratio 1.3 [95% confidence interval 1.1 to 1.5]). The estimated number needed to harm was overall 67 300 women for one intracranial meningioma. The risk increased with longer duration (≥7 years) of treatment (odds ratio, 2.1 [95% CI, 1.5 to 2.9]). Excess risk was greater in women who had previously used a progestogen with a known association to meningioma (odds ratio 3.3 [95% CI 2.6 to 4.1]). The increased risk was no longer observed one year after discontinuation of desogestrel.
Since desogestrel is metabolised to etonogestrel, the results of this study are also of clinical relevance for etonogestrel.

The product information for medicinal products containing desogestrel or etonogestrel will be updated accordingly and meningioma will be added as an adverse reaction with a frequency 'not known'.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions.
To report any suspected adverse reaction
Saudi Arabia:
Saudi Food and Drug Authority (SFDA)
The National Pharmacovigilance Centre (NPC):
SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa

In addition, suspected adverse reactions related to Aja pharma products may be reported to Aja pharma Pharmacovigilance department:
Email: PV@Ajapharma.com
Contact Person: Lama Alzaidi
Tel: +966-11-4148188 Ext 5726
Mobile +966550113712

Annexes
Regulon® Relevant sections of the Product Information that have been revised

QPPV name:
Lama Fahad Alzaidi

Signature:

Date:
28/10/2026

[1] Roland N, Kolla E, Baricault B, Dayani P, Duranteau L, Froelich S et al. Oral contraceptives with progestogens desogestrel or levonorgestrel and risk of intracranial meningioma: national case-control study. BMJ 2025; 389:e083981 doi:10.1136/bmj2024-083981