<Date>

Desogestrel- and etonogestrel-containing medicinal products: risk of meningioma and measures to minimise the risk

Dear Healthcare Professional,

<Name of marketing authorisation holders> in agreement with the European Medicines Agency and the <National Competent Authority> 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

[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/bmj-2024-083981

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 should report adverse events in accordance with the national requirements via the national spontaneous reporting system, to:

<Details (e.g., name, postal address, fax number, website address) on how to access the national spontaneous reporting system>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

DHPC COMMUNICATION PLAN

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Medicinal product(s)/active substance(s)	Desogestrel-containing medicinal products Etonogestrel-containing medicinal products
Marketing authorisation holder(s)	All concerned marketing authorisation holders of desogestrel-containing medicinal products and etonogestrel-containing medicinal products. All concerned marketing authorisation holders in each Member State are strongly encouraged to collaborate, so that a single DHPC is prepared and circulated in each Member State. The letter circulated in each Member State should cover all active substance-containing products authorised in that Member State. It is encouraged that the originator marketing authorisation holder (where available) in each Member State acts as the contact point for the national competent authority, on behalf of the other concerned marketing authorisation holders in the same Member State. If no originator product is marketed in the Member State, it is encouraged that one of the concerned generic companies acts as contact point for the competent authority.
Safety concern and purpose of the communication	Risk of meningioma
DHPC recipients	Gynaecologists, general practitioners, and nurses working in family planning clinics. The list of recipients should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	All EU member states where desogestrel-containing medicinal products and etonogestrel-containing medicinal products are authorised and marketed.

Timetable	Date
DHPC and communication plan (in English) agreed by PRAC	9 July 2026
Submission of translated DHPCs to the national competent authorities for review	23 July 2026
Agreement of translations by national competent authorities	30 July 2026
Dissemination of DHPC	6 August 2026