PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION (DHPC)

6th August 2026

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

Dear Healthcare Professional,

Organon Pharma (Ireland) Limited, Gedeon Richter (Ireland) and Sandoz (trading as Rowex Limited) Ireland in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA) 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 ethinylestradiol, 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 should report adverse events in accordance with the national requirements via the national spontaneous reporting system, to HPRA Pharmacovigilance, website: www.hpra.ie.

Suspected adverse reactions should also be reported to the relevant Marketing Authorisation Holders (see contact details below).

[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

Company contact point

If you have any questions, or if you require any further information, please contact the medical information service of the relevant Marketing Authorisation Holder.

Product Name(s)	Marketing Authorisation Holder	*Contact point details*
Azalia (desogestrel) 75 microgram film-coated tablets Gedarel extra 30 / 150 micrograms film coated tablets Gedarel 20 / 150 microgram film-coated tablets	Gedeon Richter	Gedeon Richter (Ireland) 4045 Kingswood Road Citywest Business Campus Dublin 24 Ireland Email: Medinfo.uk@gedeonrichter.eu Telephone: 0044 207 604 8800
Mercilon (desogestrel/ethinylestradiol) 150/20 microgram tablets Marviol (desogestrel/ethinylestradiol) 150/30 microgram tablets Cerazette (desogestrel) 75 microgram film coated tablets Nuvaring (etonogestrel/ethinylestradiol) 0.120/0.015 mg per 25 hours, vaginal delivery system Implanon NXT (etonogestrel) 68 mg implant for subdermal use	Organon Pharma (Ireland) Limited	Organon Pharma (Ireland) Limited, North Dock Dublin Ireland D01V4A3 Email: medinfo.ROI@organon.com Phone number: +353 1582 8260
Desogestrel Rowex 75 microgram Film-coated Tablets	Sandoz (trading as Rowex Limited) Ireland	Sandoz (trading as Rowex Limited) Ireland Medical information: mi.ireland@sandoz.com Adverse Event reporting: adverse.event.ireland@sandoz.com

Yours faithfully



Stephanie Ruhland
Deputy EU QPPV
Organon Northwest Europe

Signed on behalf of the Marketing Authorisation Holders listed in the table above