Desogestrel- and etonogestrel- containing medicines: risk of meningioma and new measures to minimise this risk

14/07/2026 | Circular Number P08/2026

Information on desogestrel- and etonogestrel- containing medicines

- Desogestrel and etonogestrel are progestogens used for contraception.
- Desogestrel-containing medicines are available as oral tablets, while etonogestrel-containing medicines are available as implants or, in combination with ethinylestradiol, as vaginal rings.
- The product information for these medicines will be updated to include meningioma as a side effect with a frequency "not known", together with new contraindications and warnings.

In Malta the following products are authorised through various licensing procedures:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
DESOGESTREL 150 microgram(s) | ETHINYLESTRADIOL 20 microgram(s)	Mercilon 150/20 microgram	Tablets	POM	MA031/02301	N.V. Organon
DESOGESTREL 0.15 milligram(s) | ETHINYLESTRADIOL 0.03 milligram(s)	Adele 0.15mg/0.03mg	Tablets	POM	AA1006/01002	Heaton k.s.
DESOGESTREL 0.075 milligram(s)	Lamya 0.075 mg film-coated	Film-Coated Tablets	POM	AA1006/00204	Heaton k.s.
DESOGESTREL 75 microgram(s)	Azalia 75 microgram film-coated	Film-Coated Tablets	POM	AA1031/01201	Gedeon Richter Plc
DESOGESTREL 0.150 milligram(s) | ETHINYLESTRADIOL 0.020 milligram(s)	Mercilon	Tablets	POM	PI770/10101B	JV Healthcare Limited
DESOGESTREL 75 microgram(s)	Cerazette 75 microgram	Film-Coated Tablets	POM	AA1606/01801	MyRX Limited

DESOGESTREL 150 microgram(s) | ETHINYLESTRADIOL 150 microgram(s)	Mercilon 150/20 microgram	Tablets	POM	PI908/12802A	NeoFarma Pharmaceuticals Limited
DESOGESTREL 75 microgram(s)	Desogestrel Rowex 75 microgram	Film-coated tablets	POM	PI908/30601A	NeoFarma Pharmaceuticals Limited
DESOGESTREL 0.075 milligram(s)	Lamya 0.075 mg	Film-coated tablets	POM	AA908/33201	NeoFarma Pharmaceuticals Limited
DESOGESTREL 75 microgram(s)	Desogestrel Rowex 75 microgram	Film-coated tablets	POM	MA1122/03301	Rowex Ltd
ETONOGESTREL 8.25 milligram(s) | ETHINYLESTRADIOL 2.60 milligram(s)	Teyla 0.120 mg/0.015mg per 24 hours	Vaginal delivery system	POM	MA1006/01901	Heaton k.s.
ETONOGESTREL 68 milligram(s)	Implanon NXT, 68 mg	Implant for subdermal use	POM	MA031/01701	N.V. Organon
ETONOGESTREL 68 milligram(s)	Implanon NXT, 68 mg	Implant for subdermal use	POM	PI770/08302B	JV Healthcare Limited
ETHINYLESTRADIOL 2.7 milligram(s) | ETONOGESTREL 11.7 milligram(s)	NuvaRing, 0.120 mg/0.015 mg per 24 hours	Vaginal delivery system	POM	MA031/02201	N.V. Organon

Information from the EMA about the safety concern

- A small increased risk of meningioma has been associated with current, prolonged use (>1 year) of desogestrel- or etonogestrel-containing contraceptive medicines.
- Although the risk is increased in people using these medicines, the overall likelihood of developing meningioma remains very low and one additional meningioma is estimated to occur for every 67,300 women who use the medicines. Meningiomas are tumours of the tissue layer surrounding the brain and spinal cord. Usually they are benign (non-cancerous) and grow slowly but, depending on the size or location, they can cause serious problems.
- ***Use of desogestrel- or etonogestrel-containing medicines is now contraindicated in women who have a meningioma or have had one in the past.***
- Women receiving these medicines should be monitored for signs and symptoms suggestive of meningioma, including changes in vision, hearing loss or ringing in the ears, loss of smell, worsening headaches, memory loss, seizures or weakness in arms and legs.

- PRAC issued these recommendations following the review of data from a large French epidemiological study. This study found a small increased risk of intracranial meningioma in women using desogestrel for one year or more, with the risk increasing with longer duration of use.
- The risk may be higher in women who previously used progestogens already associated with meningioma (for example cyproterone, nomegestrol, medroxyprogesterone, and chlormadinone). Previous progestogen use should therefore be considered before starting desogestrel or etonogestrel.
- The PRAC has agreed on a direct healthcare professional communication (DHPC) to inform healthcare professionals about this issue.

For more information visit https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-6-9-july-2026 on the European Medicines Agency's website and the SmPC for the respective products.

In Malta

For Patients

- If you are taking desogestrel- and etonogestrel- containing medicines, monitor for any changes in vision, hearing loss or ringing in the ears, loss of smell, worsening headaches, memory loss, seizures or weakness in arms and legs.
- Seek medical attention if you notice any of the above symptoms especially if you have taken desogestrel- and etonogestrel- containing medicines for more than 1 year.

For Healthcare Professionals

- Women receiving desogestrel- and etonogestrel- containing medicines should be monitored for signs and symptoms suggestive of meningioma, including changes in vision, hearing loss or ringing in the ears, loss of smell, worsening headaches, memory loss, seizures or weakness in arms and legs.
- Desogestrel- and etonogestrel-containing medicines should not be prescribed to women who have a meningioma or had one in the past.
- If a woman using desogestrel or etonogestrel is diagnosed with meningioma, use of the medicine must be discontinued.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on desogestrel- and etonogestrel- containing medicines. Suspected Adverse Drug Reactions (side effects) may be

reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate

Malta Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Malta Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Archived Safety Circulars
Archived Direct Healthcare Professional Communications
Archived Risk Minimisation Measures

Feedback Form

The Malta Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Malta Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Licence no. 656

Pharmacovigilance Section

Post-Licensing Directorate

Malta Medicines Authority

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