If undelivered please return to Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta

Ref: 03/2026/PLD
23rd July 2026

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

Dear Healthcare Professional,

Gedeon Richter Plc, HEATON k.s, JV Healthcare Limited, MyRX ltd, Neofarma Pharmaceuticals Limited, N.V. Organon, Rowex Ltd. in agreement with the European Medicines Agency and the Malta Medicines 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 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

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Malta Medicines Authority ADR reporting form available online at http://medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt

Healthcare Professionals may also report any adverse events associated with the use of desogestrel- and etonogestrel-containing medicinal products to the relevant Marketing Authorisation Holder contact points.

Company contact point

Company	Product Name	Email	Phone
Gedeon Richter Plc	Azalia 75 microgram film-coated tablets (AA1031/01201)	drugsafety.mt@gedeonrichter.com	
HEATON k.s., Na Pankráci 332/14, 140 00 Prague 4, Czech Republic	Adele 0.15 mg/0.03 mg tablets	farmakovigilance@heaton.cz	+420 602 440 229
	Lamya 0,075 mg film-coated tablets		
	Teyla 0,120 mg/0,015 mg/per 24 hours, vaginal delivery system		
JV Healthcare Limited	Mercilon	alexandra.grima@jvpharma.eu	+356 21437551
	Implanon NXT, 68 mg implant for subdermal use		
MyRX ltd	Cerazette 75 microgram film-coated tablets	galeak@myrxltd.com	+356 79220060
Neofarma Pharmaceuticals Limited	Mercilon 150/20 microgram tablets	pc@neofarma.com.mt rp@neofarma.com.mt mandy@inv.mt	+356 2010 9494
	Desogestrel Rowex 75 microgram Film-coated tablets		
	Lamya 0.075 mg film-coated tablets		
N.V. Organon, Kloosterstraat 6, Oss, Noord-Brabant, 5349 AB, Netherlands	Mercilon	pv_eei@organon.com maria.kritikou@organon.com	+35 722866730
	Nuvaring		
	Implanon NXT		
Prohealth Ltd on behalf of Rowex Ltd	Desogestrel Rowex 75 microgram Film Coated Tablet	Rowex: ie.regaffairs@sandoz.com	+356 2338 5327
		Prohealth: pharmacovigilance@prohealth.com.mt	

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of Gedeon Richter Plc, HEATON k.s, JV Healthcare Limited, MyRX ltd, Neofarma Pharmaceuticals Limited, N.V. Organon, Rowex Ltd.

The MMA receives the relevant contact details from both the Medical Council and the Pharmacy Council. Should you wish to amend your details including address, you are asked to contact the Medical Council or Pharmacy Council directly, as may apply.

For more information related to safety please refer to the below:

Archived Safety Circulars are available from: https://medicinesauthority.gov.mt/safetycirculars
Archived Direct Healthcare Professional Communications are available from: https://medicinesauthority.gov.mt/dhpc
Archived additional Risk Minimisation Measures are available from: https://medicinesauthority.gov.mt/rmm