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Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 6-9 July 2026 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found on the webpage for PRAC recommendations on safety signals (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Desogestrel; etonogestrel – Meningioma (EPITT no 20167)

Taking into account the already existing wording in some nationally authorised products, the text may need to be adapted by marketing authorisation holders to individual products.

Summary of product characteristics

4.3 Contraindications

Meningioma or history of meningioma (see section 4.4)

4.4 Special warnings and precautions for use

Meningioma

Current, prolonged use (≥1 year) of desogestrel has been associated with a small increased risk of meningioma (see sections 4.3 and 4.8). [*For etonogestrel-containing products:* Desogestrel is metabolised to etonogestrel.] The risk increased with longer duration of treatment. The risk may be higher in women with previous exposure to progestogens associated with an increased risk of meningioma, which should be considered before initiating treatment. Patients treated with <substance> should be monitored for signs and symptoms of meningioma. If a patient is diagnosed

[1] Expected publication date. The actual publication date can be checked on the webpage dedicated to PRAC recommendations on safety signals.

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with meningioma, treatment with <substance> must be discontinued. Available data suggest that the risk of meningioma may decrease after treatment discontinuation.

4.8 Undesirable effects

Neoplasms benign, malignant and unspecified

Frequency 'not known': Meningioma

Description of selected adverse reactions

Meningioma

A case-control study found that current, prolonged use (≥1 year) of desogestrel 75 µg was associated with a small increased risk of intracranial meningioma requiring surgery (odds ratio, 1.3 [95% confidence interval (CI), 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. [For etonogestrel-containing products: Since desogestrel is metabolised to etonogestrel, the results of this study are also of clinical relevance for <product name>.]

Package leaflet

2. What you need to know before you take [product name]

Do not take [product name]

- […]
- If you have meningioma or have ever been diagnosed with a meningioma (a tumour of the tissue layer surrounding the brain and spinal cord that is usually benign). See section Warnings and precautions.
- […]

Warnings and precautions

[…]

Meningiomas

Use of [active substance] has been linked to a small increased risk for tumours of the tissue surrounding the brain and spinal cord that are usually benign (meningiomas). The risk appears to increase with longer use and in women who have previously used progestogens associated with meningioma. Overall, about one additional case of meningioma is estimated to occur for every 67,300 women treated with [active substance]. If you are diagnosed with meningioma, your doctor will stop treatment with [Product name] (see section 'Do not use [Product name]'). If you notice any symptoms such as changes in vision (e.g. double vision or blurred vision), hearing loss or ringing in the ears, loss of smell, headaches that get worse over time, memory loss, seizures, or weakness in your arms or legs you must tell your doctor straight away.

[…]

4. Possible side effects

Frequency not known (cannot be estimated from the available data)

- Tumour of the tissue surrounding the brain and spinal cord that is usually benign (meningioma).

2. Levonorgestrel intrauterine device 13.5 mg – Increased risk of ectopic pregnancy (EPITT no 20251)

Summary of product characteristics

4.4 Special warnings and precautions for use

Ectopic pregnancy

[…] Data from post-authorisation observational studies report higher incidence rates of ectopic pregnancy with Jaydess (13.5 mg), compared to other IUSs and copper IUDs (see section 4.8, description of selected adverse reactions).

[…]

Because an ectopic pregnancy may ~~impact~~ compromise future fertility, the benefits and risks of using Jaydess should be carefully evaluated~~, in particular for nulliparous women~~ on an individual basis. This includes consideration of other IUSs/IUDs, particularly in women who may wish to become pregnant in the future.

~~*Use in nulliparous women:* Jaydess is not first choice for contraception in nulliparous women as clinical experience is limited.~~

4.8 Undesirable effects

c. Description of selected adverse reactions

[…]

In a nationwide cohort study using data from the French National Healthcare Data System, hormonal IUSs and copper IUDs were compared. At 1-year, ectopic pregnancy incidence rates were 0.18 (95% CI 0.14–0.23), 0.10 (95% CI 0.08–0.11), 0.04 (95% CI 0.03–0.05), and 0.07 (95% CI 0.07–0.08) per 100 person-years, for the levonorgestrel 13.5 mg, 19.5 mg, 52 mg IUSs and copper IUDs, respectively. Compared with copper IUDs, hazard ratios for ectopic pregnancy were 2.57 (95% CI 1.92–3.43), 1.37 (95% CI 1.15–1.62), and 0.62 (95% CI 0.49–0.80) for the levonorgestrel 13.5 mg, 19.5 mg, and 52 mg IUSs, respectively.

Package leaflet

2. What you need to know before you use Jaydess

[…]

Extrauterine pregnancy (pregnancy outside the womb)

[…] Real-world studies report higher risk of ectopic pregnancy with Jaydess compared with other IUSs (levonorgestrel 19.5 and 52 mg) and copper intrauterine devices (IUDs). An extrauterine pregnancy is

a serious condition, which calls for *immediate* medical attention (see section 2, "Warnings and precautions" for signs and symptoms) and may ~~impact~~ compromise future fertility.