



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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News announcement

Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6 – 9 July 2026

PRAC agrees new safety information on desogestrel- and etonogestrel-containing contraceptives and Litfulo, a medicine to treat alopecia areata

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

PRAC agreed on a direct healthcare professional communication (DHPC) to inform healthcare professionals about a small increased risk of meningioma 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 study¹. This study showed a small increased risk of intracranial meningioma in women using desogestrel for one year or longer, with the risk increasing with longer duration of use. In addition, the risk may be higher in women who previously used progestogens already associated with meningioma (for example cyproterone, norgestrel, medroxyprogesterone, and chlormadinone). Previous progestogen use should therefore be considered before starting desogestrel or etonogestrel.

If a woman using desogestrel or etonogestrel is diagnosed with meningioma, use of the medicine must be discontinued.

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.

Litfulo (ritlecitinib): update to product information to revise warnings in line with other Janus kinase inhibitors

PRAC agreed on a DHPC to inform healthcare professionals that the warnings on the potential risk of certain serious side effects with the Janus kinase (JAK) inhibitor Litfulo will be strengthened. The updated warnings are being introduced because other JAK inhibitors have an increased risk of serious side effects, including cardiovascular problems, blood clots, cancer and serious infections, and this increased risk is also considered to apply to Litfulo.

A boxed warning will be added to the Litfulo product information, stating that the medicine should be used in the following patients only if no suitable treatment alternatives are available: those aged 65 years or above, those at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past and those at increased risk of cancer. In addition, Litfulo should be used with caution in patients with risk factors for blood clots in the lungs and in deep veins (venous thromboembolism), other than those listed above.

Litfulo is a medicine used to treat adults and adolescents over 12 years of age with severe alopecia areata, an autoimmune disease causing hair loss of the scalp or other parts of the body. The active substance in Litfulo, ritlecitinib, works by blocking the action of certain enzymes called JAK3 and TEC kinases, which play an important role in inflammation.

The boxed warning is already included in the product information for other JAK inhibitors, which are used to treat certain chronic inflammatory disorders, including alopecia areata. For Litfulo,

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

the PRAC reviewed available data from clinical trials, the literature and spontaneous post-marketing reports of suspected side effects. Based on this review, and considering that Litfulo also works by inhibiting a JAK enzyme, the PRAC concluded that the product information and educational material for medicines containing ritlecitinib should be amended to include the same information as for other JAK inhibitors.

The DHPCs for desogestrel- and etonogestrel-containing medicines and for Litfulo will be disseminated to healthcare professionals by the marketing authorisation holders, according to agreed communication plans, and published on EMA's [Direct healthcare professional communications](#) page and in [national registers in EU Member States](#).

PRAC statistics: Month Year

Glossary:

Safety signal assessments. A safety signal is information which suggests a new potentially causal association, or a new aspect of a known association between a medicine and an adverse event that warrants further investigation. Safety signals are generated from several sources such as spontaneous reports, clinical studies and the scientific literature. More information can be found under '[Signal management](#)'.

Periodic safety update reports, abbreviated as PSURs, are reports prepared by the marketing authorisation holder to describe the worldwide safety experience with a medicine in a defined period after its authorisation. PSURs for medicinal products that contain the same active substance or the same combination of active substances but have different marketing authorisations and are authorised in different EU Member States, are jointly assessed in a single assessment procedure. More information can be found under '[Periodic safety update reports: questions and answers](#)'.

Risk management plans, abbreviated as RMPs, are detailed descriptions of the activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicines. Companies are required to submit an RMP to EMA when applying for a marketing authorisation. RMPs are continually updated throughout the lifetime of the medicine as new information becomes available. More information is available under '[Risk-management plans](#)'.

Post-authorisation safety studies, abbreviated as PASSs, are studies carried out after a medicine has been authorised to obtain further information on its safety, or to measure the effectiveness of risk-management measures. The PRAC assesses the protocols (aspects related to the organisation of a study) and the results of PASSs. More information can be found under '[Post-authorisation safety studies](#)'.

Referrals are procedures used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. In a referral related to safety of medicines, the PRAC is requested by a Member State or the European Commission to conduct a scientific assessment of a particular medicine or class of medicines on behalf of the EU. More information can be found under [referral procedures](#).

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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