14 September 2023
EMA/CHMP/402803/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ryeqo

relugolix / estradiol / norethisterone acetate

On 14 September 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Ryeqo. The marketing authorisation holder for this medicinal product is Gedeon Richter Plc.

The CHMP adopted a new indication for the symptomatic treatment of endometriosis. For information, the full indications for Ryeqo will be as follows:[2]

> Ryeqo is indicated in adult women of reproductive age for:
>
> - treatment of moderate to severe symptoms of uterine fibroids,
> - **symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis.**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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