20 May 2021
EMA/CHMP/126766/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ryeqo

relugolix / estradiol / norethisterone acetate

On 20 May 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ryeqo, intended for the treatment of symptoms of uterine fibroids. The applicant for this medicinal product is Gedeon Richter Plc.

Ryeqo will be available as 40-mg / 1-mg / 0.5-mg film-coated tablets. The active substances of Ryeqo are relugolix / estradiol / norethisterone acetate. Relugolix belongs to the therapeutic group of anti-gonadotrophin-releasing hormones (ATC code: H01CC54) and reduces release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH) through its action at GnRH receptors. Giving it with estradiol alleviates symptoms associated with a hypoestrogenic state, such as vasomotor symptoms and bone mineral density loss. The addition of a progestogen reduces the oestrogen-induced risk of endometrial hyperplasia in non-hysterectomised women.

The benefits with Ryeqo are its ability to reduce heavy menstrual bleeding associated with uterine fibroids. The most common side effects are hot flush and uterine bleeding.

The full indication is:

> Ryeqo is indicated for treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

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