28 June 2018
EMA/CHMP/417636/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ulipristal Acetate Gedeon Richter

ulipristal acetate

On 28 June 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ulipristal Acetate Gedeon Richter, intended for the pre-operative treatment of uterine fibroids. The applicant for this medicinal product is Gedeon Richter Plc.

Ulipristal Acetate Gedeon Richter will be available as 5-mg tablets. The active substance of Ulipristal Acetate Gedeon Richter is ulipristal acetate, a selective progesterone receptor modulator (ATC code: G03XB02) that acts by depriving uterine fibroids of growth stimulation due to progesterone.

The benefits with Ulipristal Acetate Gedeon Richter are its ability to reduce fibroid-related bleeding, anaemia and fibroid size. The most common side effects are amenorrhea, endometrial thickening and hot flush.

The application for Ulipristal Acetate Gedeon Richter was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Ulipristal Acetate Gedeon Richter is Esmya.

The full indication is: "Ulipristal acetate is indicated for one treatment course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Ulipristal acetate is indicated for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age who are not eligible for surgery."

It is proposed that Ulipristal Acetate Gedeon Richter be prescribed by physicians experienced in the diagnosis and treatment of uterine fibroids.

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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