29 January 2026
EMA/CHMP/24373/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Fylrevy

estetrol

On 29 January 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Fylrevy, intended as hormone replacement therapy (HRT) to treat women who have been through the menopause and experience symptoms associated with oestrogen deficiency.

The applicant for this medicinal product is Gedeon Richter Plc.

Fylrevy will be available as 14.2 mg and 18.9 mg film-coated tablets. The active substance of Fylrevy is estetrol, a sex hormone and modulator of the genital system (ATC code: G03CA10). Estetrol substitutes for the loss of oestrogen production in women who have gone through the menopause and alleviates symptoms associated with the menopause, including vasomotor symptoms (VMS).

The benefit of Fylrevy is a statistically significant reduction in the frequency and severity of moderate to severe VMS in women who have gone through the menopause, compared with placebo, as shown in two randomised double-blind, placebo-controlled multicentre clinical trials.

The most common side effects in women who have been through the menopause, have not undergone hysterectomy, had not had menses for at least 12 months, and were treated with Fylrevy in combination with progesterone, include endometrial thickening, vaginal haemorrhage and disordered proliferative endometrium. The other most common side effects with Fylrevy regardless of whether women had undergone hysterectomy, include breast tenderness and breast pain.

The full indication is:

> Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in hysterectomised postmenopausal women.
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> Hormone replacement therapy (HRT) for oestrogen deficiency symptoms in non-hysterectomised postmenopausal women with at least 12 months since last menses.

Detailed recommendations for the use of this product will be described in the summary of product

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.