EMA/30106/2026
EMEA/H/C/006213

Fylrevy (*estetrol*)

A plain-language overview of Fylrevy and why it is authorised in the EU

What is Fylrevy and what is it used for?

Fylrevy is a medicine used for hormone replacement therapy (HRT) in women who have gone through the menopause to help relieve symptoms, such as hot flushes, caused by low blood levels of the female hormone oestrogen.

It is used in women who have not had their uterus (womb) removed and have not had a menstrual period for at least 12 months, and in women who had their uterus removed.

Fylrevy contains the active substance estetrol.

How is Fylrevy used?

Fylrevy can only be obtained with a prescription. It is available as tablets to be taken by mouth once a day at about the same time. For women who still have their uterus, the doctor will also prescribe a medicine containing a progestogen hormone to be taken with Fylrevy. Fylrevy is available in two strengths, and the doctor should always prescribe the lowest effective dose for the shortest duration necessary to relieve symptoms.

For more information about using Fylrevy, see the package leaflet or contact your doctor or pharmacist.

How does Fylrevy work?

During menopause, oestrogen levels decline, which can lead to symptoms such as hot flushes.

The active substance of Fylrevy, estetrol, is a synthetic (man-made) version of an oestrogen that is naturally present in women during pregnancy. The medicine works by replacing the oestrogen hormone the body no longer produces after the menopause, helping to relieve symptoms associated with the menopause, such as hot flushes.

What benefits of Fylrevy have been shown in studies?

Two main studies involving 1,225 women showed that Fylrevy is effective at reducing the number and severity of hot flushes associated with menopause.

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

In the first study, after 12 weeks of treatment, the average number of weekly moderate-to-severe hot flushes decreased by about 60 in women taking the low dose Fylrevy and 66 in those taking the high dose, compared with a decrease of 43 in women given placebo (a dummy treatment). Women taking Fylrevy also reported a greater improvement in the severity of hot flushes, compared with women taking placebo.

In the second study, after 12 weeks of treatment, the average number of weekly moderate-to-severe hot flushes decreased by 58 and 61 in women taking the low and high dose Fylrevy, compared with 45 in women given placebo.

What are the side effects and restrictions with Fylrevy?

For the full list of side effects and restrictions with Fylrevy, see the package leaflet.

The most common side effects with Fylrevy (which may affect up to 1 in 10 women), include breast tenderness and breast pain.

For women who have been through the menopause, still have their uterus and have not had a menstrual period for at least 12 months, the most common side effects with Fylrevy in combination with progesterone 100 mg (which may affect more than 1 in 10 women) include endometrial thickening (thickening of the lining of the womb) and vaginal haemorrhage (bleeding). Disordered proliferative endometrium (abnormal growth of the lining of the womb) may affect up to 1 in 10 women.

Fylrevy must not be used in women who:

- have, have previously had or are suspected of having breast cancer or a cancer that is sensitive to oestrogens, such as cancer of the womb lining;
- have abnormal vaginal bleeding whose cause has not been diagnosed or excessive thickening of the womb lining that is not being treated;
- have or have ever had any problems with blood clots, including clots in the veins (such as deep vein thrombosis or pulmonary embolism), conditions that make the blood more likely to clot, or serious illnesses caused by clots in the arteries (such as a heart attack or stroke);
- have or have ever had severe liver disease and their liver function tests have not returned to normal;
- have a rare inherited blood disease called porphyria.

Why is Fylrevy authorised in the EU?

Fylrevy was shown to be effective at treating hot flushes in women who have been through the menopause. The side effects with Fylrevy were considered manageable. The European Medicines Agency therefore decided that the benefits of Fylrevy are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Fylrevy?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Fylrevy have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Fylrevy are continuously monitored. Suspected side effects reported with Fylrevy are carefully evaluated and any necessary action taken to protect patients.

Other information about Fylrevy

Fylrevy received a marketing authorisation valid throughout the EU on 26 March 2026.

Further information on Fylrevy can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/fylrevy.

This overview was last updated in 04-2026.