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Ryeqo (*relugolix / estradiol / norethisterone acetate*)

An overview of Ryeqo and why it is authorised in the EU

What is Ryeqo and what is it used for?

Ryeqo is a medicine used to treat moderate to severe symptoms of uterine fibroids (non-cancerous growths in the womb) in women of reproductive age.

Ryeqo contains the active substances relugolix, estradiol and norethisterone acetate.

How is Ryeqo used?

Ryeqo is available as tablets. The recommended dose is one tablet a day at around the same time each day. Treatment should begin within 5 days from the start of a menstrual period to avoid initial irregular or heavy bleeding. After starting the treatment, Ryeqo can be taken without interruption.

All other hormonal contraceptive methods must be stopped before starting Ryeqo, which provides adequate contraception after at least one month of use.

The medicine can only be obtained with a prescription. For more information about using Ryeqo, see the package leaflet or contact your doctor or pharmacist.

How does Ryeqo work?

One of the active substances in Ryeqo, relugolix, blocks the pituitary gland (a gland that controls many other hormone-producing glands in the body) from releasing luteinizing hormone and follicle-stimulating hormone, which in turn prevents the production of progesterone and decreases the production of oestrogen. Progesterone and oestrogen are hormones that are involved in fibroid growth.

Another active substance of Ryeqo, estradiol, is a natural sex hormone that helps to reduce symptoms related to the lowered levels of oestrogen, such as hot flushes and bone density loss. However, estradiol used alone can cause hyperplasia (growth) of the endometrium (the lining of the womb), which could lead to endometrial cancer. Ryeqo, therefore, also contains the active substance norethisterone acetate, a synthetic progesterone replacement that blocks the effects of estradiol on the womb, reducing the risk of endometrial growth.

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

What benefits of Ryeqo have been shown in studies?

Ryeqo has been shown to be effective in treating symptoms linked to uterine fibroids in two studies involving pre-menopausal women aged 18 to 50 with heavy menstrual bleeding. In both studies, around 500 women received either Ryeqo or placebo (a dummy treatment) for 24 weeks.

In the first study, 73% (94 out of 128) of women using Ryeqo reported monthly menstrual blood loss of fewer than 80 mL and at least 50% less blood loss than before the treatment, compared with 19% (24 out of 128) of those taking placebo. In the second study, 71% (89 out of 126) achieved this reduction in the volume of blood lost while using Ryeqo, compared with 15% (19 out of 129) of those given the placebo.

What are the risks associated with Ryeqo?

The most common side effects with Ryeqo (which may affect up to 1 in 10 people) are hot flushes and bleeding from the womb.

Ryeqo must not be used in women who have, or have had, venous thromboembolism (blood clots in the veins) or those who have had a stroke or a heart attack. It must also not be used in women who have a blood clotting disorder, osteoporosis, migraines or headaches with neurological symptoms, cancers that are influenced by sex hormones (such as breast cancer or genital cancer), liver tumours, or abnormal liver function, or in those who are pregnant, breastfeeding or have genital bleeding of unknown cause.

Ryeqo must not be used together with hormonal contraception.

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

Why is Ryeqo authorised in the EU?

Symptoms linked to uterine fibroids can be serious and debilitating. Ryeqo was shown to be effective at reducing moderate to severe symptoms of uterine fibroids, such as heavy periods, with manageable side effects. Therefore, the European Medicines Agency decided that Ryeqo's benefits 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 Ryeqo?

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

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

Other information about Ryeqo

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

This overview was last updated in 06-2021.