

Summary report on authorisation dated 17 December 2025

Ryeqo[®] (active substances: relugolix, estradiol, norethisterone acetate)

Indication extension in Switzerland: 30 April 2025

Film-coated tablets for the treatment of pain due to endometriosis

About the medicinal product

The medicinal product Ryeqo, containing the active substances relugolix, estradiol and norethisterone acetate, is used for the treatment of moderate to severe pain caused by endometriosis.

Endometriosis is a painful disease in which the uterine lining (endometrium) grows outside the uterus. Women with endometriosis can suffer from pain during menstruation, non-menstrual pelvic pain and/or pain during sexual intercourse.

Ryeqo was first authorised by Swissmedic on 2 February 2023 for the treatment of heavy menstrual bleeding due to uterine fibroids in premenopausal women.

This indication extension means that Ryeqo can now be used for endometriosis-associated pain in women who have had an inadequate response to progestogen therapy or who are ineligible for progestogen therapy.

Mode of action

Ryeqo contains three active substances: relugolix, which suppresses the formation of oestrogen and progesterone by the ovaries. Ryeqo also contains the oestrogen estradiol and the progestogen norethisterone. The addition of these two hormones helps to mitigate potential side effects.

Estradiol reduces the hot flushes that occur if relugolix is taken on its own (see also "Precautions, undesirable effects & risks"). Norethisterone protects the lining of the uterus against the possible consequences of higher estradiol levels.

Administration

Ryeqo is a prescription-only medicine.

Ryeqo is available as film-coated tablets. Each film-coated tablet contains 40 mg

relugolix, 1 mg estradiol, and 0.5 mg norethisterone acetate. The recommended dose is one film-coated tablet daily. The tablets should be taken with a little liquid.

Treatment starts within the first 5 days after the onset of menstrual bleeding. Ryego is then taken once daily at the same time each day without a break.

Efficacy may be impaired if it is taken with a high-fat meal.

Hormonal contraceptives must be discontinued before starting treatment with Ryego. Non-hormonal contraceptive methods must be used during treatment and for at least 1 month after discontinuing Ryego.

Efficacy

The efficacy of Ryego in treating pain during endometriosis was investigated in two multinational studies (SPIRIT 1 and 2), each lasting 24 weeks. Overall, 1261 patients aged 18 to 50 years with confirmed endometriosis and moderate to severe pain participated in these studies, which investigated the extent to which Ryego reduced both pain during menstruation and non-menstrual pelvic pain. The results showed that Ryego reduced

menstrual pain by around 75 % and non-menstrual pelvic pain by around 50 % compared to placebo. On completion of both studies, the patients were able to continue the treatment in an extension study. Overall, the studies lasted for up to 2 years. The efficacy of Ryego in reducing endometriosis-associated pain was maintained throughout this period.

Precautions, undesirable effects & risks

Ryego must not be used in those who are hypersensitive to the active substances or any of the excipients.

The most common undesirable effects (affecting more than 1 in 10 of those treated) are headache (13%) and hot flushes (10%).

A bone density scan is recommended for patients with risk factors for osteoporosis before starting treatment with Ryego. This scan should then be repeated after the first

year of treatment, and thereafter every 2 years.

Pregnancy must be ruled out prior to starting treatment.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Endometriosis is a common disease in women of childbearing age. This disease can lead to severe pain and other stressful symptoms.

The studies showed that patients with endometriosis benefit from Ryego. Endometriosis-associated pain (during and independently of menstruation) was significantly reduced by Ryego compared to placebo.

Taking all the risks and precautions into account, and based on the available data, the benefits of Ryego outweigh the risks. Swissmedic has therefore authorised the medicinal product Ryego, containing the active substances relugolix, estradiol and norethisterone acetate, in Switzerland for the treatment of endometriosis-associated pain.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals Ryeqo®](#)

Healthcare professionals can answer any further questions.

Information for patients (package leaflet):
[Information for patients Ryeqo®](#)

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.