

Public Summary SwissPAR dated 28 March 2024

## Ryeqo<sup>®</sup> (active substances: relugolix, estradiol, norethisterone acetate)

First authorisation in Switzerland: 2 February 2023

Film-coated tablets for the treatment of heavy menstrual bleeding due to uterine fibroids

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### About the medicinal product

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The medicinal product Ryeqo contains a combination of the 3 active substances relugolix, estradiol, and norethisterone acetate, and is used in adult women before they enter the menopause to treat heavy menstrual bleeding due to uterine fibroids.

Fibroids are benign, hormone-sensitive tumours of the uterus. They are the most common tumours of the female reproductive organs. Their growth is promoted by oestrogen, among other things, but progesterone also plays a role in their development. Risk factors include being overweight, high blood pressure, and family history. Women who have never been pregnant are also at higher risk of fibroids. The frequency of fibroids increases with age up until the menopause; by contrast, these growths can shrink spontaneously after the menopause.

Only around a quarter of women affected develop symptoms requiring treatment. The most frequently treated symptom is heavy and/or persistent menstrual bleeding (HMB). This can result in iron deficiency, which can lead to fatigue and anaemia. HMB is also often more painful than normal menstrual bleeding, and the pain often lasts for longer than normal. The quality of life of women affected can therefore be severely impaired.

Until recently, surgical interventions such as hysterectomy in particular were the most widely used treatment option for fibroids. Availability of medicinal products to treat fibroid-related symptoms has been very limited to date.

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### Mode of action

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The key active substance in Ryeqo is relugolix, which suppresses the formation of oestrogen and progesterone by the ovaries. This lowers oestrogen and progesterone

levels in the blood, reducing fibroid-related HMB.

Ryeqo also contains the oestrogen estradiol and the progestogen norethisterone. The addition of these two hormones helps to

mitigate potential side effects. Estradiol reduces hot flushes that occur if relugolix alone is taken (see also “Precautions, unde-

sirable effects, & risks”). Norethisterone protects the lining of the uterus against the possible consequences of higher estradiol levels.

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## Administration

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Ryeqo is a prescription-only medicine.

It is available as a pack of 28 film-coated tablets in 1 bottle or 84 film-coated tablets in 3 bottles. Each film-coated tablet contains 40 mg relugolix, 1 mg estradiol, and 0.5 mg norethisterone acetate. The recommended dose is 1 tablet daily.

Treatment starts within the first 5 days after the onset of menstrual bleeding. Ryeqo is

then taken once daily at the same time each day without a break.

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

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## Efficacy

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The efficacy of Ryeqo was compared to a placebo (dummy drug) in 2 studies (LIBERTY 1 and 2) involving 770 female patients, initially over a period of 6 months. The participating patients were between 18 and 50 years old but still pre-menopausal and had heavy menstrual bleeding with high blood loss due to fibroids.

Ryeqo reduced the monthly blood loss due to menstrual bleeding by 84% compared to placebo. Patients then continued to be treated with Ryeqo in further studies. These studies lasted for a total of 2 years. The efficacy of Ryeqo was maintained during this period.

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## Precautions, undesirable effects, & risks

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

The most frequent undesirable effects are hot flushes (8%) and uterine bleeding (5%).

A bone density scan is recommended for patients with risk factors for osteoporosis before starting treatment with Ryeqo. 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.

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## Why the medicinal product has been authorised

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Fibroids can result in considerable impairment of quality of life due to heavy and painful menstrual bleeding in around one quarter of women affected. The studies show that patients with fibroids and heavy menstrual bleeding benefit from Ryego. Monthly blood loss is reduced significantly.

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, for use in Switzerland.

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## Further information on the medicinal product

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

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

Healthcare professionals can answer any further questions.

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 Public Summary SwissPAR.

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