

APPROVED

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MOCK-UP

Package Leaflet: Information for the User

Ryeqo® 40 mg/1 mg/0.5 mg film-coated tablets

(relugolix/estradiol/norethisterone acetate)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Your medicine is known by the above name, but will be referred to as Ryeqo® throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ryeqo® is and what it is used for
2. What you need to know before you take Ryeqo®
3. How to take Ryeqo®
4. Possible side effects
5. How to store Ryeqo®
6. Contents of the pack and other information

1. WHAT RYEQO® IS AND WHAT IT IS USED FOR

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

It is used to treat

- moderate to severe symptoms of uterine fibroids (commonly known as myomas), which are non-cancerous tumours of the uterus (womb).
- symptoms associated with endometriosis in women with a history of previous medical or surgical treatment for their endometriosis (endometriosis is an often painful disorder in which tissue similar to the tissue that normally lines the inside of your uterus - the endometrium - grows outside your uterus).

Ryeqo® is used in adult women (over 18 years of age) before they reach menopause.

In some women, uterine fibroids may cause heavy menstrual bleeding (your 'period') and pelvic pain (pain below the belly button). Ryeqo® is used for the treatment of your fibroids to stop or reduce bleeding and to decrease pain and pelvic discomfort associated with uterine fibroids.

Women with endometriosis can experience pelvic or lower abdominal pain, pain with menstrual periods and pain with intercourse. Ryeqo® is used for the treatment of endometriosis to decrease the symptoms due to displaced tissue of the lining of the womb.

This medicine contains relugolix, which blocks certain receptors in the brain and this reduces the production of hormones that in turn stimulate the ovaries to produce estradiol and progesterone. When blocked, the levels of estrogen and progesterone circulating in the body are reduced. This medicine also contains two types of female hormones, estradiol which belongs to a group of medicines called estrogens and norethisterone which belongs to a group of medicines called progestogens. The inclusion of these hormones in Ryeqo® maintains a hormonal state similar to the beginning of your menstrual cycle and thus relieves your symptoms while helping to protect the strength of your bones.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RYEQO®**Do not take Ryeqo®**

Do not take Ryeqo® if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor:

- if you are **allergic** to relugolix, estradiol, norethisterone acetate or any of the other ingredients of this medicine (listed in section 6).
- if you have or previously have had a **blood clot in a blood vessel** in the legs (deep vein thrombosis), lungs (pulmonary embolism), heart (heart attack), brain (stroke) or any other parts of the body.

- if you have or previously have had a disease caused by blood clots in the arteries, such as a **heart attack, stroke** or **angina**.
- if you have a **blood clotting disorder** (such as protein C deficiency, protein S deficiency, antithrombin-III deficiency, or Factor V Leiden).
- if you have **osteoporosis**.
- if you suffer from **headaches** with focal neurological symptoms such as paralysis or loss of muscle control, or **migraines** with visual disturbance.
- if you have any type of **cancer** which might be made worse by exposure to female sex hormones, such as **cancer of the breast or the genital organs**.
- if you have or ever had **liver tumours**.
- if you have or ever had a **liver disease** and your **liver function tests** have not returned to normal.
- if you are **pregnant** or if you think you **might be pregnant** or if you are **breastfeeding**.
- if you have any **genital bleeding** of unknown origin.
- if you are taking **hormonal contraception** (for example birth control pills) and unwilling to discontinue its use.

If any of the above conditions appear for the first time while taking Ryeqo®, stop taking it at once and consult your doctor immediately.

If you are not sure about any of the points above, talk to your doctor before taking Ryeqo®.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ryeqo®.

You should know that most women have reduced or no menstrual bleeding (period) during treatment and for a few weeks afterwards.

Your doctor will discuss your medical and family history with you. Your doctor will also need to check your blood pressure and make sure you are not pregnant. You may also need a physical examination and additional checks, such as breast examination and a scan to measure how strong your bones are, that will be specific to your medical needs and/or concerns.

Stop taking Ryeqo® and get urgent medical attention if you notice:

- any of the conditions mentioned in the "Do not take Ryeqo®" section.
- if you notice signs of **liver disease**:
 - yellowing of your skin or the whites of your eyes (jaundice).
 - nausea or vomiting, fever, severe tiredness.
 - dark urine, itching or upper abdominal pain.
- a large rise in your **blood pressure** (symptoms may be headache, tiredness, dizziness).
- **migraine** for the first time or unusually bad **headaches** occurring more often than before.
- if you notice possible signs of a **blood clot** that may mean you are suffering from a clot in the leg (i.e. deep vein thrombosis), or in the lung (i.e. pulmonary embolism), a heart attack or a stroke. For a description of the symptoms of these serious conditions please go to 'Ryeqo® and risk of blood clots'.
- if you become **pregnant**.

Tell your doctor if any of the following conditions apply to you:

- if you have one or more of the **risk factors for developing a blood clot** listed below.
- if you have **high blood pressure**.
- if you have **osteoporosis**.
- if you suffer from **migraines**.
- if you think you might be **pregnant**. Treatment with Ryeqo® usually leads to a significant reduction or may even stop your menstrual bleeding (your 'period'), making it difficult to recognise pregnancy.
- if you have or previously suffered from **depression**.
- if you have **renal (kidney) disease**.

Ryeqo® and risk of blood clots

The use of other medicines containing an estrogen and a progestogen increases the risk of blood clots. The risk of blood clots with Ryeqo® has not been established. Ryeqo® reduces the estrogen to levels similar to those at the beginning of your normal menstrual cycle.

Factors that can increase your risk of a blood clot in your vein and/or artery:

- as you get **older** (particularly above about 35 year of age).
- if you are **overweight** (body mass index > 30 kg/m²).
- if you have had **major surgery** or **prolonged time off your feet** (e.g. your leg is in a cast).

- if you have **recently given birth**.
- if anyone in your close family has had a **blood clot in the leg, lung or other organ**, a **heart attack** or a **stroke at a young age** (e.g. below the age of 50 years).
- if you **smoke**.
- if you have a problem with your heart (**valve disorder**, disturbance of the rhythm called **atrial fibrillation**).
- if you have **diabetes**.
- if you have certain medical conditions such as **systemic lupus erythematosus** (SLE - a disease affecting your natural defence system), **sickle cell disease** (an inherited disease of the red blood cells), **Crohn's disease** or **ulcerative colitis** (chronic inflammatory bowel diseases), or **cancer**.

The risk of developing a blood clot increases the more factors you have.

The symptoms of a blood clot will depend on where the blood clot has occurred.

*Symptoms of a blood clot in your leg (**deep vein thrombosis; DVT**)*

The symptoms of a blood clot in the leg known as a deep vein thrombosis (DVT) can include:

- swelling in your leg and/or foot or along a vein in your leg.
- pain or tenderness in your leg which feels worse when you stand up or are walking.
- increased heat in the affected leg with red or discoloured skin.

*Symptoms of a blood clot in your lung (**pulmonary embolism; PE**)*

The symptoms of a blood clot in the lung known as a pulmonary embolism (PE) can include:

- a sudden onset of unexplained shortness of breath or rapid breathing.
- sudden coughing which may be associated to a sharp pain in your chest.
- coughing up of blood.
- severe dizziness or feeling lightheaded.
- a rapid or irregular heartbeat.

*Symptoms of a **heart attack***

The symptoms of a heart attack, also known as a myocardial infarction, may be temporary and can include:

- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in your chest, arm, or below your breastbone.
- discomfort radiating to your back, jaw, throat, arm, stomach.
- feeling of being full, having indigestion or choking.
- sweating, nausea, vomiting or dizziness.
- extreme weakness, anxiety, or shortness of breath.
- rapid or irregular heartbeats.

*Symptoms of a **stroke***

The symptoms of a stroke can include:

- a sudden numbness or weakness in your face, arm of leg, especially on one side of your body.
- sudden trouble walking, dizziness, loss of balance or coordination.
- sudden confusion, trouble speaking or understanding others.
- sudden trouble seeing in one or both of your eyes.
- sudden, severe or prolonged headache with no known cause.
- loosing consciousness or fainting with or without a seizure.

Surgery

If you are going to have surgery, tell the surgeon that you are taking Ryeqo®.

Liver tumours or liver disease

In rare cases liver tumours or liver disease has been reported in women taking estrogens and progestogens. If you experience any symptoms of jaundice contact your doctor for further medical advice.

Renal (kidney) impairment

If you experience any decrease in urine production or notice any fluid retention causing swelling in your legs, ankles or feet, please contact your doctor for further medical advice.

Change in menstrual bleeding pattern (your ‘period’)

Treatment with Ryeqo® usually leads to a significant reduction or may even stop your menstrual bleeding (your ‘period’) within the first 30 days of treatment. However, if you continue to experience excessive bleeding, tell your doctor.

Depression

If you experience mood changes or any depressive symptoms contact your doctor for further medical advice.

Increased blood pressure

In rare cases treatment with Ryeqo® may lead to small increases in blood pressure. If you experience any symptoms of increased blood pressure, contact your doctor for further medical advice.

Uterine fibroid prolapse and expulsion

Uterine fibroids may develop anywhere within the muscular wall of the uterus, including the submucosa, a thin layer of tissue in the uterus. In some women, the uterine fibroid may protrude or slip through the cervix into the vagina and may lead to significant worsening of uterine bleeding or pain. If you re-experience severe uterine bleeding after your symptoms have improved while being treated with Ryeqo®, contact your doctor for medical advice.

Gallbladder disorders

Some women taking estrogen and progestogen hormones including Ryeqo® have reported gallbladder disorders (gallstones or inflammation of your gallbladder). If you experience unusually severe pain below your rib cage or in your upper abdomen contact your doctor for medical advice.

Children and adolescents

Ryeqo® should not be taken by children under 18 years of age since the safety and efficacy of Ryeqo® has not been established in this age group.

Other medicines and Ryeqo®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Talk to your doctor if you are taking any of the medicines listed below, as these medicines can affect Ryeqo® or be affected by Ryeqo®:

- Certain medicines used to treat **epilepsy** (e.g. carbamazepine, topiramate, phenytoin, phenobarbital, primidone, oxcarbazepine, felbamate).
- Certain medicines used to treat human immunodeficiency virus infection/ acquired immunodeficiency syndrome (**HIV/AIDS**) (e.g. ritonavir, efavirenz).
- Certain medicines used to treat **Hepatitis C virus (HCV)** (e.g. boceprevir, sofosbuvir, velpatasvir, voxilaprevir, telaprevir, glecaprevir).
- Certain medicines used to treat **fungal infections** (e.g. ketoconazole, itraconazole, fluconazole, griseofulvin).
- Certain medicines used to treat **bacterial infections** (e.g. rifampicin, rifabutin, clarithromycin, erythromycin, gentamicin, tetracycline, griseofulvin).
- Certain medicine used to treat **high blood pressure in the arteries in the lung** (e.g. bosentan).
- Certain medicines used to treat **high blood pressure** (e.g. diltiazem, carvedilol, verapamil).
- Certain medicines used to treat **irregular heartbeats** (e.g. amiodarone, dronedarone, propafenone, quinidine, verapamil).
- Certain medicines used to treat **angina** (e.g. ranolazine, carvedilol, verapamil).
- Certain medicines to prevent organ rejection **after transplantation** (e.g. cyclosporine).
- Herbal remedies containing **St John’s wort** (*Hypericum perforatum*).

Pregnancy and breast-feeding

Do not take Ryeqo® if you are pregnant or breast-feeding. If you think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. If you become pregnant, stop taking Ryeqo® and contact your doctor.

Ryeqo® stops ovulation and thus you are not likely to become pregnant while using Ryeqo® if used as recommended. Ovulation and menstrual bleeding will return rapidly after discontinuing Ryeqo® and alternative birth control needs to be started immediately after discontinuation of Ryeqo®.

Depending on when in your cycle you start taking Ryeqo®, it may take time to obtain the full inhibition of ovulation by Ryeqo®; therefore, nonhormonal birth control (e.g. condoms) should be used for the first month after starting Ryeqo®.

If you miss two or more tablets in a row, nonhormonal birth control (e.g. condoms) should be used for the next 7 days of treatment.

Driving and using machines

Ryeqo® has no known effect on the ability to drive and use machines.

Laboratory tests

If you need a blood or urine test, tell your doctor or the laboratory staff that you are taking Ryeqo® because this medicine can affect the results of some tests.

Ryeqo® contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Ryeqo®

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet per day.

The tablet must be taken orally every day, at about the same time, with or without food with a little liquid.

It is recommended that you start taking Ryeqo® within the first 5 days after the start of bleeding due to your period. If you start at another time of your menstrual cycle, you may initially experience irregular or heavier bleeding.

If you take more Ryeqo® than you should

There have been no reports of serious harmful effects from taking several doses of this medicine at once. Large doses of estrogen may cause nausea and vomiting, and vaginal bleeding. If you have taken too many Ryeqo® tablets ask your doctor or pharmacist for advice.

If you forget to take Ryeqo®

If you miss one tablet, take it as soon as you remember and then resume taking your tablet the next day as usual. Do not take a double dose to make up for a forgotten tablet.

If you miss two or more tablets in a row, consult with your doctor and use a nonhormonal contraceptive (e.g. condoms) for the next 7 days of treatment.

If you stop taking Ryeqo®

If you would like to stop taking Ryeqo®, talk to your doctor first. Your doctor will explain the effects of stopping treatment and discuss other possibilities with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Get urgent medical attention if you get any of the following signs and symptoms of an allergic reaction:

- swelling of your lips, face or throat.

The following side effects have been reported with Ryeqo® and are listed below according to the frequency which they occur.

Very common side effects (may affect more than 1 in 10 people)

- headache,
- hot flush.

Common side effects (may affect up to 1 in 10 people):

- irritability,
- decreased interest in sex,
- dizziness,
- nausea,
- hair loss,
- increased sweating,
- night sweats,
- joint pain,
- excessive, irregular, or prolonged bleeding from the womb (uterine bleeding),
- dryness of the genital area.

Uncommon side effects (may affect up to 1 in 100 people):

- indigestion,
- hives (urticaria),
- angioedema (rapid swelling of the mucous membranes or the skin that may occur in the face, mouth, tongue, abdomen or arms and legs),
- a lump in the breast tissue (breast cyst),

- uterine myoma expulsion (fibroid comes out either completely or partially through the vagina, usually with increased bleeding from the vagina).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE RYEQO®

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ryeqo® contains

- The active substances are relugolix, estradiol and norethisterone acetate.
- Each film-coated tablet contains 40 mg relugolix, 1 mg estradiol (as hemihydrate) and 0.5 mg norethisterone acetate.
- The other ingredients are lactose monohydrate, mannitol (E421), sodium starch glycolate, hydroxypropyl cellulose (E463), magnesium stearate (E572), hypromellose type 2910 (E464), titanium dioxide (E171), triacetin (E1518), iron oxide yellow (E172).

What Ryeqo® looks like and contents of the pack

Ryeqo® is light yellow to yellow, round, film-coated tablet of 8 mm with “415” on one side, and plain faced on the other side. It is available in PVC/Al blister with desiccant packed in PET/Al/PE triplex foil sachet.

Each box contains 28 or 84 tablets, divided into two or six blister packs of 14 tablets each.

Manufactured by Gedeon Richter Plc., Gyomroi ut 19-21, 1103 Budapest, Hungary.

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