

# Ryeqo<sup>®</sup> 40/1/0.5 (Ryeqo)

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I taking Ryeqo?

Ryeqo contains the active ingredients, relugolix, estradiol hemihydrate and norethisterone acetate. Ryeqo is taken to treat adult women (over the age of 18 years) before they reach menopause for moderate to severe symptoms of uterine fibroids (commonly known as myomas), and for symptomatic treatment of endometriosis in women with a history of previous medical or surgical treatment for their endometriosis.

For more information, see Section [1. Why am I taking Ryeqo?](#) in the full CMI.

### 2. What should I know before I take Ryeqo?

Do not use if you have ever had an allergic reaction to Ryeqo or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take Ryeqo?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Ryeqo and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take Ryeqo?

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

More instructions can be found in Section [4. How do I take Ryeqo?](#) in the full CMI.

### 5. What should I know while taking Ryeqo?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Ryeqo.</li><li>• Tell your doctor if you have any medical conditions, take any medicines for any other condition, or are planning on having surgery.</li><li>• Tell your doctor if you become pregnant whilst taking Ryeqo.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking Ryeqo before talking to your doctor first.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Ryeqo affects you.</li><li>• Ryeqo has no known effect on the ability to drive and use machines.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor <i>if</i> you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store Ryeqo in a cool dry place where the temperature is below 30°C.</li><li>• Store it in a cool dry place away from moisture, heat, or sunlight.</li><li>• Keep it where young children cannot reach it.</li></ul>

For more information, see Section [5. What should I know while taking Ryeqo?](#) in the full CMI.

### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Ask your doctor or pharmacist if you have any further questions about side effects. The most common side effects are headaches, hot flushes, excessive, irregular, or prolonged bleeding from the womb (uterine bleeding), hair loss, decreased interest in sex, irritability, increased sweating, a lump in the breast tissue (breast cyst), indigestion, night sweats, back pain, joint pain, genital area dryness. Serious side effects include uterine myoma expulsion.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Ryeqo<sup>®</sup> 40/1/0.5 (Ryeqo) (Re-echo)

**Active ingredients:** *relugolix, estradiol, norethisterone acetate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking Ryeqo. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Ryeqo.**

**Where to find information in this leaflet:**

- [1. Why am I taking Ryeqo?](#)
- [2. What should I know before I take Ryeqo?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Ryeqo?](#)
- [5. What should I know while taking Ryeqo?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking Ryeqo?

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

**It is used to treat adult women (over 18 years of age) before they reach menopause for:**

- moderate to severe symptoms of uterine fibroids (commonly known as myomas)**
- symptomatic treatment of endometriosis who have 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 (endometrium) grows outside of your uterus.

Relugolix reduces the production of hormones from the ovaries, reducing the amount of estrogen and progesterone circulating in the body.

Estradiol and norethisterone acetate are two types of female hormones added in Ryeqo to maintain a hormonal state similar to the beginning of your period.

Relugolix, estradiol, and norethisterone acts to relieve your symptoms of uterine fibroids or endometriosis.

## 2. What should I know before I take Ryeqo?

### Warnings

**Do not take Ryeqo if:**

- you are allergic to relugolix, estradiol or norethisterone or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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.
- you have or previously had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina.
- you have a blood clotting disorder (such as protein C deficiency, protein S deficiency, antithrombin-III deficiency, or Factor V Leiden).
- you have osteoporosis.
- you suffer from headaches with focal neurological symptoms such as paralysis or loss of muscle control, or migraine with visual disturbance.
- you have had any tumour that is made worse by exposure to female sex hormones such as breast cancer or cancer of the genital organs.
- you have or have had a liver disease and your liver function tests have not returned to normal.
- you have or ever had liver tumour.
- you are pregnant or think you may be pregnant.
- you are breastfeeding.
- you have any genital bleeding of unknown origin.
- you are taking hormonal contraceptives and are unwilling to discontinue its use.

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 (called a DXA scan) to measure how strong your bones are, that will be specific to your medical needs and/or concerns.

### Bone loss (decreased bone mineral density)

Taking Ryeqo can cause bone loss. For this reason, your doctor may order a DXA scan to check your bone mineral density when you start taking Ryeqo and periodically thereafter.

You may be at higher risk of experiencing bone loss under certain conditions, such as having a history of low-trauma fracture, having risk factors for osteoporosis or taking medications that decrease bone density (e.g. systemic or chronic inhaled corticosteroids, anticonvulsants, or chronic use of proton pump inhibitors).

#### Stop taking Ryeqo and get urgent medical attention if:

- you notice any of the conditions mentioned in Section [2. What should I know before I take Ryeqo?](#) under 'Do not take Ryeqo 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.
- you notice **migraine** for the first time or unusually bad **headaches** occurring more often than before.
- 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 Section [6. Are there any side effects?](#) under [Serious side effects](#).
- you become **pregnant**.

#### Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.

#### 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 years of age).
- if you are overweight (body mass index > 30 kg/m<sup>2</sup>).

- 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.

Go to Section [6. Are there any side effects?](#) under [Serious side effects](#) for symptoms:

- of a blood clot in your leg,
- of a blood clot in your lung,
- of a heart attack,
- of a stroke.

#### 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.

Signs and symptoms of depression may include:

- feeling overwhelmed by sadness that persists throughout the day for 2 weeks or more and often involves sleep and appetite changes.

## 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.

## Ryeqo contains lactose

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 taking 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. There are no data on fertility following treatment with Ryeqo in women with endometriosis.

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

If you miss your doses for 2 or more consecutive days, non-hormonal birth control (e.g. condoms) should be used for the next 7 days of treatment.

Do not take Ryeqo if you are breastfeeding.

You should know that most women have reduced or no periods during treatment and for a few weeks afterwards after medication is ceased.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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)
- 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. sofosbuvir, velpatasvir, voxilaprevir, 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, 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*)

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins, or supplements you are taking and if these affect Ryeqo.**

## 4. How do I take Ryeqo?

### How much to take

- Each daily dose is one tablet.
- Follow the instructions provided and take Ryeqo until your doctor tells you to stop.

### When to take Ryeqo

- 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.

### How to take Ryeqo

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

### If you forget to take Ryeqo

Ryeqo should be taken regularly at about the same time each day. If you miss your dose at the usual time, take it as soon as you remember and then resume taking your tablet the next day as usual.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

If you miss a dose for 2 or more consecutive days use nonhormonal contraception for the following 7 days.

### If you take too much Ryeqo

If you think that you have taken too much Ryeqo, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking Ryeqo?

### Things you should do

#### Call your doctor straight away if you:

- experience any of the side effects listed below and they worry you.
- find out you are pregnant.

Remind any doctor, dentist, or pharmacist you visit that you are taking Ryeqo.

You should use a non-hormonal contraceptive for at least one month after starting treatment.

### Things you should not do

- Do not stop taking this medicine before talking to your doctor first. Your doctor will explain the effects of stopping treatment and discuss other possibilities with you.

### 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.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Ryeqo affects you.**

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

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

- Store Ryeqo below 30°C

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>General</b></p> <ul style="list-style-type: none"> <li>• headache</li> <li>• hot flush</li> <li>• excessive, irregular, or prolonged bleeding from the womb (uterine bleeding)</li> <li>• hair loss</li> <li>• decreased interest in sex</li> <li>• irritability</li> <li>• increased sweating</li> <li>• a lump in the breast tissue (breast cyst)</li> <li>• night sweats</li> <li>• back pain</li> <li>• joint pain</li> <li>• dryness of the genital area</li> <li>• hives</li> </ul> <p><b>Gastrointestinal</b></p> <ul style="list-style-type: none"> <li>• indigestion</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• <b>Uterine myoma expulsion</b> (fibroid comes out either completely or partially through the vagina, usually with increased bleeding from the vagina).</li> <li>• <b>Angioedema</b> (rapid swelling of the bottom layer of skin on the face (including eyelids, lips, swelling on the arms, legs, or genitals), or swelling of the tongue, or throat, potentially leading to breathing difficulties).</li> <li>• <b>Blood clots</b> The signs of blood clots will depend on where the blood clot has occurred.  <b>Symptoms of a blood clot in your leg (deep vein thrombosis)</b> The symptoms of a blood clot in the leg known as a deep vein thrombosis (DVT) can include:</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>– swelling in your leg and/or foot or along a vein in your leg.</li> <li>– pain or tenderness in your leg which feels worse when you stand up or are walking.</li> <li>– increased heat in the affected leg with red or discoloured skin.</li> </ul> <p><b>Symptoms of a blood clot in your lung (pulmonary embolism)</b> The symptoms of a blood clot in the lung known as a pulmonary embolism (PE) can include:</p> <ul style="list-style-type: none"> <li>– a sudden onset of unexplained shortness of breath or rapid breathing.</li> <li>– sudden coughing which may be associated to a sharp pain in your chest.</li> <li>– coughing up of blood.</li> <li>– severe dizziness or feeling lightheaded.</li> <li>– a rapid or irregular heartbeat.</li> </ul> <ul style="list-style-type: none"> <li>• <b>Symptoms of a heart attack</b> The symptoms of a heart attack, also known as a myocardial infarction, may be temporary and can include:</li> </ul> <ul style="list-style-type: none"> <li>– pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in your chest, arm, or below your breastbone.</li> <li>– discomfort radiating to your back, jaw, throat, arm, stomach.</li> <li>– feeling of being full, having indigestion or choking.</li> <li>– sweating, nausea, vomiting or dizziness.</li> <li>– extreme weakness, anxiety, or shortness of breath.</li> <li>– rapid or irregular heartbeats.</li> </ul> <ul style="list-style-type: none"> <li>• <b>Symptoms of a stroke</b> The symptoms of a stroke can include:</li> </ul> <ul style="list-style-type: none"> <li>– a sudden numbness or weakness in your face, arm of leg, especially on one side of your body.</li> <li>– sudden trouble walking, dizziness, loss of balance or coordination.</li> </ul>	

Serious side effects	What to do
<ul style="list-style-type: none"> <li>– sudden confusion, trouble seeing in one or both your eyes.</li> <li>– sudden, severe or prolonged headache with no known cause.</li> <li>– losing consciousness or fainting with or without a seizure.</li> </ul> <ul style="list-style-type: none"> <li>• <b>Increased blood pressure</b> Symptoms of increased blood pressure may include headache, tiredness, dizziness.</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What Ryeqo contains

<b>Active ingredients (main ingredients)</b>	<ul style="list-style-type: none"> <li>• relugolix</li> <li>• estradiol hemihydrate</li> <li>• norethisterone acetate</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• lactose monohydrate</li> <li>• mannitol (E421)</li> <li>• sodium starch glycollate</li> <li>• hypolose (E463)</li> <li>• magnesium stearate (E572)</li> <li>• hypromellose type 2910 (E464)</li> <li>• titanium dioxide (E171)</li> <li>• triacetin (E1518)</li> <li>• iron oxide yellow (E172)</li> </ul>
<b>Potential allergens</b>	lactose monohydrate

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Ryeqo looks like

Ryeqo is a light yellow to yellow, round, film-coated tablet, with "415" on one side and plain faced on the other side.

Ryeqo is available in bottles of 28 film-coated tablets (1x bottle) or 84 film-coated tablets (3x bottles).

Not all pack sizes may be marketed.

The Australian Registration Number is AUST R 375414.

### Who distributes Ryeqo?

Ryeqo is supplied in Australia by:

Gedeon Richter Australia Pty Ltd  
Suite 902/15 Blue Street  
North Sydney NSW 2060  
Australia

Phone: 1300 GEDEON (1300 433 366)

This leaflet was prepared in January 2024.