

Esomeprazole RBX

Consumer Medicine Information (CMI) summary

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

1. Why am I using Esomeprazole RBX?

Esomeprazole RBX contains the active ingredient esomeprazole magnesium. Esomeprazole RBX is used to treat reflux oesophagitis, Upper gastrointestinal symptoms associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs) therapy, Peptic ulcers associated with *Helicobacter pylori* infection, Zollinger-Ellison syndrome, Prevention of rebleeding of gastric or duodenal ulcers.

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

2. What should I know before I use Esomeprazole RBX?

Do not use if you have ever had an allergic reaction to Esomeprazole RBX 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 use Esomeprazole RBX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Esomeprazole RBX 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 use Esomeprazole RBX?

- Take one Esomeprazole RBX tablet each day, unless your doctor has told you otherwise. The dose of Esomeprazole RBX tablet is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.
- Follow the instructions provided and use Esomeprazole RBX until your doctor tells you to stop.

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

5. What should I know while using Esomeprazole RBX?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Esomeprazole RBX.• Tell your doctor if your symptoms return.• If you need to have any medical tests while you are taking Esomeprazole RBX, tell your doctor. |
| Things you should not do | <ul style="list-style-type: none">• Do not take it to treat any other complaints unless your doctor tells you to.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours. |
| Driving or using machines | Esomeprazole RBX is not likely to affect the ability to drive or use machines. |
| Looking after your medicine | <ul style="list-style-type: none">• Keep it in a cool, dry place where the temperature stays below 25°C. |

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

6. Are there any side effects?

Common side effects include headache, stomach pain, constipation, diarrhea, wind, nausea, vomiting, itching, skin rash, dizziness, dry mouth, swelling of hands, ankles or feet. These side effects are usually mild. Serious side effects rare.

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.

Esomeprazole RBX

Active ingredient(s): *esomeprazole magnesium*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using Esomeprazole RBX?

Esomeprazole RBX contains the active ingredient esomeprazole magnesium. Esomeprazole RBX is a type of medicine called a proton-pump inhibitor. It works by decreasing the amount of acid made by the stomach to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Esomeprazole RBX is used for the followings:

Reflux oesophagitis

Esomeprazole RBX is taken to treat reflux oesophagitis. This can be caused by 'washing back' (reflux) of food and acid from the stomach into the food pipe (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Esomeprazole RBX is also taken to help stop reflux oesophagitis coming back or relapsing.

Upper gastrointestinal symptoms associated with Non-steroidal Anti-inflammatory Drugs (NSAIDs) therapy

Esomeprazole RBX is taken to treat the symptoms of pain or discomfort in the stomach caused by the NSAIDs, a type of medicine for pain or inflammation.

Esomeprazole RBX is also taken to help heal and prevent ulcers caused by NSAIDs.

Peptic ulcers associated with *Helicobacter pylori* infection

Most people who have a peptic (gastric and duodenal) ulcer also have a bacterium called *Helicobacter pylori* in their stomach. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

If you have a peptic ulcer, your doctor will prescribe Esomeprazole RBX with antibiotics. When Esomeprazole RBX and antibiotics are taken together, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

Zollinger-Ellison syndrome

Esomeprazole RBX is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amount of acid, much more than in ulcers or reflux disease.

Prevention of rebleeding of gastric or duodenal ulcers

Esomeprazole RBX is also used as prolonged treatment after prevention of rebleeding of ulcers of stomach or gut with intravenous esomeprazole.

When peptic ulcers become severe enough, they start to bleed. You may receive treatment injected into your veins initially. This treatment may be followed with Esomeprazole RBX for a longer period of time. This is to help ulcer/s to heal.

2. What should I know before I use Esomeprazole RBX?

Warnings

Do not use Esomeprazole RBX if:

- you are allergic to esomeprazole magnesium, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicines containing a proton-pump inhibitor.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face lips, tongue or other parts of the body; rash, itching or hives on the skin.

- Always check the ingredients to make sure you can use this medicine.
- you are taking atazanavir or cilostazol

Please check with your doctor or pharmacist if you are taking these medicines. These medicines will be affected by Esomeprazole RBX.

- the use by (expiry) date printed on the pack passed or if the packaging is torn or shows signs of tampering.

If it has expired or damaged, return it to your pharmacist for disposal.

Check with your doctor if you:

- have any other medical conditions:
 - liver
 - experienced any significant weight loss, difficulty in swallowing or dark tarry stools
 - severe kidney problems

- any other medical conditions
- being diagnosed with osteoporosis
- if you have ever had a skin reaction after treatment with a medicine similar to Esomeprazole RBX that reduces stomach acid.
- allergies to any other medicines, foods, dyes or preservatives

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

Do not take Esomeprazole RBX if you are pregnant or breast-feeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

It is not known if it is safe for you to take Esomeprazole RBX while you are pregnant. It may affect your baby.

It is not known if your baby can take in Esomeprazole RBX from breast milk if you are breastfeeding.

Children younger than 1 year:

Esomeprazole RBX is not approved for use in children younger than 1 year of age.

There is no specific information about use in children younger than 1 year of age, so Esomeprazole RBX is not recommended in these patients.

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.

Do not take Esomeprazole RBX if you are taking the following medicines:

- atazanavir and nelfinavir (used to treat HIV)
- cilostazol (used to reduce leg pain when walking caused by blood circulation disease)

Some medicines may interfere with Esomeprazole RBX. These include:

- medicines used to treat fungal infections such as ketoconazole, itraconazole and voriconazole
- medicines used to treat bacterial infections such as clarithromycin and rifampicin
- cisapride
- diazepam, a medicine used to treat anxiety and some other conditions
- phenytoin, a medicine used to treat epilepsy
- medicines used to treat depression such as citalopram, clomipramine or imipramine
- warfarin and clopidogrel- medicines used to prevent blood clots
- digoxin, a medicine used to treat certain heart problems
- medicines for HIV treatment such as nelfinavir

- St. John's Wort, a herbal remedy used to treat mood disorders
- methotrexate, a medicine used to treat arthritis and some types of cancer
- tacrolimus and mycophenolate mofetil- a medicine used to assist in organ transplants
- erlotinib or related medicines used to treat cancer

These medicines may be affected by Esomeprazole RBX or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines.

Your doctor can tell you what to do if you are taking other medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Esomeprazole RBX.

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

4. How do I use Esomeprazole RBX?

How much to take/ use

- Take one Esomeprazole RBX tablet each day, unless your doctor has told you otherwise.

The dose of Esomeprazole RBX tablet is usually 20 mg or 40 mg a day depending on what condition you are being treated for and how severe it is.

- Follow the instructions provided and use Esomeprazole RBX until your doctor tells you to stop.

When to take / use Esomeprazole RBX

- Esomeprazole RBX should be taken at about the same time each day.

Keeping a regular time for taking Esomeprazole RBX will help to remind you to take it.

- Esomeprazole RBX can be taken with food or on an empty stomach.

Keep taking Esomeprazole RBX for as long as your doctor recommends.

In most patients, Esomeprazole RBX relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking Esomeprazole RBX for as long as your doctor tells you to.

How to take Esomeprazole RBX

Swallow Esomeprazole RBX tablets whole with a glass of water. Do not crush or chew the tablets. If the tablets are chewed or crushed they will not work properly.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water. Mineral water or other liquids are not suitable.
2. Gently mix the tablet and water by stirring, taking care not to crush the tablet.
3. Stir until the tablet dissolves into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.

5. Rinse the glass with half a glass of water and drink.
If you cannot swallow at all, follow steps 1-3 above to disperse the tablets and administer the liquid and pellets through a gastric tube.

If you forget to use Esomeprazole RBX

Esomeprazole RBX should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

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 have trouble remembering when to take your medicines, ask your pharmacist for some hints.

If you use too much Esomeprazole RBX

If you think that you have used too much Esomeprazole RBX, 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 using Esomeprazole RBX?

Things you should do

- Take Esomeprazole RBX exactly as your doctor has prescribed.
- If you are about to start on any new medicine, tell you doctor, dentist or pharmacist that you are taking Esomeprazole RBX
- Tell all doctors, dentists and pharmacists who are treating you that you are taking Esomeprazole RBX
- Tell your doctor if you become pregnant while you are taking Esomeprazole RBX.
- Tell your doctor if your symptoms return.

Although Esomeprazole RBX can heal ulcers, successfully, it may not prevent them recurring at a later date.

- If you need to have any medical tests while you are taking Esomeprazole RBX, tell your doctor.

It may affect the results of some tests.

Things you should not do

- Do not take it to treat any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Driving or using machines

Esomeprazole RBX is not likely to affect the ability to drive or use machines.

Looking after your medicine

- **Keep your Esomeprazole RBX in the blister pack until it is time to take them.**

If you take Esomeprazole RBX out of the blister pack It will not keep well.

- **Keep it in a cool, dry place where the temperature stays below 25°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 window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use 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 |
|--|---|
| <ul style="list-style-type: none"> • headache • stomach pain • constipation • diarrhoea • wind • nausea • vomiting • itching • skin rash • dizziness • dry mouth • swelling of hands, ankles or feet | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |
| <ul style="list-style-type: none"> • disturbances in vision (blurred vision) • feeling depressed • mood changes, agitation, aggression, hallucination • confusion | <p>Speak to your doctor immediately if you have any of these side effects.</p> |

| | |
|--|---|
| <ul style="list-style-type: none"> • muscle pain or weakness • increase in breast size (males) • increased sweating • changes in sleep patterns • fever • increased bruising • tremor • blood in the urine • hair loss • irregular (slow or fast) heartbeat • liver problems (often seen as yellowing of your skin or the whites of your eyes, feeling generally unwell, nausea, vomiting, loss of appetite) • difficulty in breathing (bronchospasm) • tingling, pricking or numbness of the hands and feet (“pins and needles”) • taste disturbance, sore mouth, thrush • skin reaction, especially in sun exposed areas, with joint pain • frequent infections such as fever, severe chills, sore throat or mouth ulcers • | <p>These are rare or very rare side effects.</p> <p>These side effects may require medical attention.</p> |
|--|---|

Serious side effects

| Serious side effects | What to do |
|--|--|
| <ul style="list-style-type: none"> • loss of consciousness or awareness • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin. • signs of liver inflammation including yellowing of the skin, eyes, feeling generally unwell, nausea, vomiting or loss of appetite • increased or decreased urine output. | <p>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.</p> |
| <ul style="list-style-type: none"> • pain or indigestion during treatment with Esomeprazole RBX • you begin to vomit blood or food • you pass black (blood-stained) motions | <p>Contact your doctor immediately if you notice any of these side effects</p> |

Occasionally, Esomeprazole RBX may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

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. 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 Esomeprazole RBX contains

| | |
|---|---|
| Active ingredient (main ingredient) | Esomeprazole magnesium |
| Other ingredients (inactive ingredients) | Non Pareil Seeds 40-60 [sugar spheres (sucrose and maize starch); Proprietary ingredient # 108075], hyprollose, crospovidone, povidone, macrogol 400, purified talc, hypromellose phthalate, diethyl phthalate, macrogol 6000, microcrystalline cellulose, sodium stearyl-fumarate, macrogol 4000 and Opadry Complete Film Coating System 03B86651 Brown (Proprietary Ingredient # 106495). |
| Potential allergens | Contains sucrose |

Esomeprazole RBX tablets do not contain lactose, glucose or gluten.

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

What Esomeprazole RBX looks like

Esomeprazole RBX 20 mg (Aust R 184759) tablet is light brick red to brown, oval, biconvex, enteric-coated tablet with 'E5' debossed on one side and plain on other side.

Esomeprazole RBX 40 mg (AUST R 184765) tablet is light brick red to brown, oval, biconvex, enteric-coated tablet with 'E6' debossed on one side and plain on other side.

Who distributes Esomeprazole RBX

Sun Pharma ANZ Pty Ltd

12 Waterloo Road Macquarie Park NSW 2113

Email: customerservice.aus@sunpharma.com

Tel. no. 1800 726 229

This leaflet was prepared in August 2025.