

APO-Rabeprazole Tablets

Rabeprazole sodium

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about rabeprazole. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may want to read it again.

What this medicine is used for

Rabeprazole is used to treat reflux oesophagitis, peptic ulcers and chronic gastritis. It belongs to a group of medicines called proton pump inhibitors (PPIs).

Reflux oesophagitis

This can be caused by food and acid from the stomach flowing the wrong way (reflux) back up the food pipe (oesophagus). Reflux can cause a burning sensation in the chest rising up to the throat (heartburn).

Rabeprazole also helps to stop reflux oesophagitis from coming back.

Peptic ulcers

This can be caused by the stomach making too much acid. It is called a gastric (stomach) or duodenal ulcer depending on the position of the

ulcer. People who have a peptic ulcer may also have bacteria called *Helicobacter pylori* in their stomach. Taking antibiotics will kill *Helicobacter pylori* and allow the ulcer to heal.

Chronic Gastritis

Helicobacter pylori may inflame the stomach, resulting in pain, nausea and vomiting. Taking antibiotics will kill *Helicobacter pylori* and allow the stomach to heal.

How it works

Rabeprazole works by decreasing the amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place. Your food is still digested in the same way.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- rabeprazole
- other proton pump inhibitors (e.g. omeprazole, esomeprazole, lansoprazole, pantoprazole)

- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any liver problems.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved. It is not known if rabeprazole passes into breast milk.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor and pharmacist if you are taking any other medicines, including any that you

get from your pharmacy, supermarket or health food shop.

Some medicines may interact with rabeprazole. These include:

- atazanavir, a medicine used to treat HIV-1 infection
- clopidogrel, an antiplatelet medicine
- cyclosporin or mycophenolate mofetil, used for immune system problems
- methotrexate, used for psoriasis and rheumatoid arthritis
- digoxin, used for heart problems
- ketoconazole or clarithromycin, used to treat infections

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

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

Other medicines not listed above may also interact with rabeprazole.

How to take this medicine

Follow all directions given to you by your doctor carefully.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is one 20 mg taken once a day. The dose may vary from 10 mg to 40 mg per day depending on your condition.

For treating Helicobacter pylori infections in combination with antibiotics, the dose is one tablet taken twice a day.

How to take it

Swallowed the tablet whole with a glass of water. Do NOT crush or chew the tablets.

They have a special coating, which protects them from the acid in your stomach. If the coating is broken by chewing, the tablets may not work.

When to take it

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it with or without food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough medicine to last over weekends and holidays.

If you forget to take it

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

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you become pregnant whilst taking rabeprazole, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without first checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking rabeprazole.

This medicine helps most people but may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache, dizziness

- stomach complaints, such as diarrhoea, constipation, stomach pain, flatulence (wind), nausea, vomiting
- dry mouth
- runny or blocked nose, sore throat and discomfort when swallowing, cough
- back pain, muscle weakness
- insomnia
- breast enlargement in men

If you experience any of the following, stop taking rabeprazole and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching, blisters or hives on the skin (signs of an allergic reaction)
- chest pain
- bleeding or bruising more easily than normal
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers

The above list includes serious side effects and you may need medical attention or hospitalisation.

Other problems are more likely to arise from the ulcer itself rather than the treatment. Contact your doctor immediately if you notice any of the following:

- pain or indigestion
- vomiting blood or food
- black (blood-stained) motions

Under rare circumstances

supervised by the doctor, proton pump inhibitors (PPIs) might be used for long periods of time. Some side effects that may occur after prolonged use include:

- low magnesium. Symptoms can include seizures, dizziness, spasms, cramps or muscle weakness
- increased risk of fractures of the hip, wrist, or spine
- vitamin B-12 deficiency

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Available in blister packs of 30 tablets. AUST R 245233.

* Not all strengths may be available.

Ingredients

Each tablet contains 10 mg or 20 mg of rabeprazole sodium as the active ingredient.

It also contains the following:

- light magnesium oxide
- mannitol
- sodium starch glycollate Type A
- povidone
- magnesium stearate
- ethylcellulose
- diethyl phthalate
- hypromellose phthalate
- titanium dioxide
- purified talc
- iron oxide red (10 mg tablets only)
- iron oxide yellow (20 mg tablets only)

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

<http://arrotex.com.au/>

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Storage and disposal

Storage

Tablets are packaged in a double-sided aluminium blister strip.

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of the pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

10 mg tablets:

Pink coloured, round, biconvex tablets, plain on both sides.

Available in blister packs of 28 tablets. AUST R 245232.

20 mg tablets:

Yellow coloured, round, biconvex, plain on both sides.