

APO-Rabeprazole Tablets

Contains the active ingredient rabeprazole (as rabeprazole sodium)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Rabeprazole tablets. It contains the active ingredient rabeprazole (as rabeprazole sodium).

It is used to treat:

- Reflux Oesophagitis or reflux disease
This can be caused by food and acid from the stomach flowing the wrong way (reflux) back up the food pipe, also known as the oesophagus.
Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.
This medicine is also used to help stop reflux oesophagitis from coming back or relapsing.
- Peptic ulcers
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 of the stomach.
These ulcers can be caused by too much acid being made in the stomach.
Most people who have a peptic ulcer also have a bacteria called *Helicobacter pylori* in their stomach. Your doctor may also prescribe a course of antibiotics

(clarithromycin and amoxicillin) for you. When this medicine is taken with antibiotics, the combination therapy will kill the *Helicobacter pylori* and let your ulcer heal.

- Chronic Gastritis
The presence of the bacteria *Helicobacter pylori* may cause the stomach to become inflamed, resulting in pain, nausea and vomiting.
When this medicine is taken with antibiotics, they will help kill *Helicobacter pylori* and allow the stomach to heal.

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 available only with a doctor's prescription.

How it works

Rabeprazole belongs to a group of medicines called proton pump inhibitors (PPIs). 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 will still be digested in the normal way.

There is no evidence that this medicine is addictive.

Use in children

This medicine is not recommended for use in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, rabeprazole, other proton pump inhibitors (e.g. omeprazole, esomeprazole, lansoprazole, pantoprazole) or any of the ingredients listed at the end of this leaflet.**

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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions
 - liver disease.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

4. You are currently breastfeeding or you plan to breast-feed. It is not known if rabeprazole passes into breast milk. Do not take this medicine until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with rabeprazole.

Tell your doctor if you are taking any of the following:

- atazanavir, a medicine used (with other antiretrovirals) to treat HIV-1 infection.
- clopidogrel, an antiplatelet medicine.

You should not take rabeprazole while taking these medicines.

Also tell your doctor if you are taking any of the following:

- cyclosporin, a medicine used to treat several conditions including prevention of graft rejection following kidney, liver or heart transplantation; severe, active rheumatoid arthritis; severe skin diseases; kidney disease where other treatments have failed.
- methotrexate, a medicine used to treat some kinds of cancer. It is also used to treat psoriasis (skin disease) and rheumatoid arthritis.
- digoxin, a medicine used to treat heart problems.
- ketoconazole, a medicine used to treat fungal infections.
- clarithromycin, a medicine used to treat infections.
- mycophenolate mofetil, a medicine used to prevent organ rejection following transplants.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with rabeprazole.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

The usual dose is one tablet at the same time each day. For treating *Helicobacter pylori* infections in combination with antibiotics (clarithromycin and amoxicillin), the dose is one tablet twice each day, morning and evening.

The usual dose is 20 mg, but may vary from 10 mg to 40 mg per day depending on what condition you are being treated for and how severe it is.

How to take it

Swallowed the tablet whole, with a glass of water or other liquid.

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

It does not matter if you take it before, with or after 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 missed dose and take your next dose at the usual time. 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 to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is

working and to prevent side effects.

Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Possible side effects

Rabeprazole is usually well tolerated but tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking rabeprazole or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- headache
- dizziness
- diarrhoea
- constipation
- stomach pain
- flatulence (wind)
- dry mouth
- nausea
- vomiting
- constipation
- runny or blocked nose
- sore throat and discomfort when swallowing

- cough
- infection
- chest pain
- back pain
- muscle weakness
- insomnia
- breast enlargement in men
- rash or itchy rash accompanied by skin eruption and blisters

Under rare circumstances supervised by the doctor, proton pump inhibitors (PPIs) might be used for long periods of time.

Low magnesium can occur in some people who take a proton pump inhibitor. Symptoms of low magnesium can include: seizures, dizziness, spasms, cramps or muscle weakness.

People who take proton pump inhibitor medicines at high doses for a long period of time (1 year or longer) may have an increased risk of fractures of the hip, wrist, or spine.

Proton pump inhibitors may reduce the amount of acid in your stomach. Stomach acid is needed to absorb vitamin B-12 properly. Talk with your doctor or pharmacist about the possibility of vitamin B-12 deficiency if you have been taking a proton pump inhibitor for a long time (i.e. more than 3 years).

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These may be serious side effects and you may need medical attention or hospitalisation:

- bleeding or bruising more easily than normal
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion
- you begin to vomit blood or food
- you pass black (blood-stained) motions.
- Other side effects not listed above may occur in some patients.

Ask your doctor or pharmacist if you do not understand anything in this list.

Allergic reactions

If you think you are having an allergic reaction to rabeprazole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Tablets may be packaged in either a clear blister strip in an aluminium pouch with a desiccant sachet, or in a double-sided aluminium blister strip.

Tablets that are packaged in the clear blister strips should be kept in the original aluminium pouch with the desiccant after opening. Any remaining tablets should be discarded 1 month after the aluminium foil pouch is opened.

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Rabeprazole looks like

New Formulation

10 mg tablets:

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

Available in blister packs of 28 tablets.

20 mg tablets:

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

Available in blister packs of 30 tablets

* Not all strengths may be available.

Old Formulation

10 mg tablets:

Pink, round, biconvex enteric coated tablets.

Available in blister packs of 28 tablets.

20 mg tablets:

Yellow, round, biconvex enteric coated tablets.

Available in blister packs of 30 tablets

* Not all strengths may be available.

Ingredients

New Formulation

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

It also contains the following inactive ingredients:

- light magnesium oxide
- mannitol
- sodium starch glycolate 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 is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Old Formulation

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

It also contains the following inactive ingredients:

- mannitol
- hydroxypropylcellulose
- hypromellose phthalate
- hypromellose
- sodium stearyl fumarate
- calcium hydroxide
- dibutyl sebacate
- purified talc
- titanium dioxide

- iron oxide yellow

iron oxide red (10 mg tablets) This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

New Formulation

APO-Rabeprazole 10 mg tablet
(Blister): AUST R 245232.

APO-Rabeprazole 20 mg tablet
(Blister): AUST R 245233.

Sponsor

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