

Rabeprazole Sandoz®

Rabeprazole (as sodium) enteric coated tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Rabeprazole Sandoz.

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 taking 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 need to read it again.

WHAT RABEPRAZOLE SANDOZ IS USED FOR

This medicine contains the active ingredient rabeprazole sodium. Rabeprazole belongs to a group of medicines called proton pump inhibitors (PPIs). It 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.

Gastro-oesophageal reflux disease (GORD)

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.

Rabeprazole sodium is also used to help stop reflux oesophagitis from coming back or relapsing.

Gastric and duodenal 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 amoxycillin) 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; all of which are signs of chronic gastritis.

When this medicine is taken with antibiotics, it will help kill *Helicobacter pylori* and allow the stomach to heal.

Your doctor may have prescribed Rabeprazole Sandoz for another reason. Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

This medicine is not addictive.

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

BEFORE YOU TAKE RABEPRAZOLE SANDOZ

When you must not take it

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

- rabeprazole sodium
- any of the ingredients listed at the end of this leaflet
- other proton pump inhibitors (omeprazole, esomeprazole, lansoprazole, pantoprazole)

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.

Do not take this medicine if:

- the expiry date (month and year) printed on the pack has passed. If you take Rabeprazole Sandoz after the expiry date it may not work
- the packaging is torn or shows signs of tampering.

Rabeprazole Sandoz should not be given to children under 18 years of age. Safety and effectiveness of Rabeprazole Sandoz in children has not been established.

Before you start to take it

You must tell your doctor if:

- you are pregnant or intend to become pregnant
- you are breastfeeding or intend to breastfeed. It is not known if Rabeprazole Sandoz passes into breast milk
- you have or have ever had liver disease.

If you have not told your doctor about any of the above, tell him/her before you start taking Rabeprazole Sandoz.

Taking other medicines

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

Do not take Rabeprazole Sandoz and tell your doctor or pharmacist 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 Sandoz while taking these medicines.

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

- ciclosporin, 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 to treat psoriasis (skin disease) and rheumatoid arthritis.
- digoxin, a medicine used to treat heart problems

- ketoconazole, a medicine used to treat fungal infections
- mycophenolate mofetil, a medicine used to prevent organ rejection following kidney, liver or heart transplants
- clarithromycin, a medicine used to treat infections.

These medicines may be affected by Rabeprazole Sandoz or may affect how well it works. Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Rabeprazole Sandoz.

Your doctor will advise you whether or not to take Rabeprazole Sandoz or if you need to have your dose adjusted.

HOW TO TAKE RABEPRAZOLE SANDOZ

Follow the directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

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

How much to take

Adults

The usual dose is one tablet, to be taken once daily, at the same time each day.

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

For treating *Helicobacter pylori* infections in combination with antibiotics (clarithromycin and amoxycillin), the dose is one 20mg tablet twice each day, morning and evening, for 7 days.

Children

Rabeprazole Sandoz should not be given to children under 18 years of age. Safety and effectiveness of Rabeprazole Sandoz in children has not been established.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

How to take it

- Rabeprazole Sandoz should be swallowed 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.
- It does not matter if you take Rabeprazole Sandoz with food or on an empty stomach.

Ask your doctor or pharmacist for help if you do not understand the instructions provided with this medicine.

If you forget to take it

If you forget to take your tablet take it as soon as you remember, and then continue to take it as you would normally.

However, 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 that you missed.

If you are not sure what to do, check with your doctor or pharmacist.

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

If you have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE TAKING RABEPRAZOLE SANDOZ

Things you must do

- Use Rabeprazole Sandoz exactly as your doctor has prescribed
- Always swallow Rabeprazole Sandoz tablets whole
- Tell your doctor if you become pregnant while you are taking Rabeprazole Sandoz.

Tell your doctor or pharmacist that you are taking Rabeprazole Sandoz if you are about to start taking a new medicine.

Things you must not do

- Do not take Rabeprazole Sandoz to treat any other complaint unless your doctor tells you to
- Do not give this medicine to anyone else, even if they have the same symptoms as you
- Do not crush or chew the tablets
- Do not give this medicine to children.

Tell your doctor if you need to have a specific blood test (Chromogranin A) while you are taking Rabeprazole Sandoz

It may affect the results of this test.

SIDE EFFECTS

Rabeprazole Sandoz 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 Sandoz.

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.

Ask your doctor or pharmacist to answer any questions you may have.

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

- headache
- dizziness
- diarrhoea
- nausea
- stomach pain
- wind
- vomiting
- constipation
- indigestion
- belching
- runny or blocked nose
- sore throat and discomfort when swallowing
- cough
- pain (including chest, back or joint pain)
- muscle weakness, physical weakness or lack of energy
- rash or itchy rash accompanied by skin eruption or blisters
- flu-like symptoms
- sleeplessness (insomnia)
- dry mouth
- leg cramps
- swelling of the arms or legs
- nervousness
- sleepiness (somnolence)
- loss of appetite for food (anorexia)
- weight gain

- sweating

These side effects are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- painful and/or frequent urination (common symptoms of a urinary tract infection)
- vision or taste disturbance
- depression
- feeling dizzy, faint, lightheaded or weak (hypotension)
- shortness of breath
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

Tell your doctor immediately and do not take your next dose of Rabeprazole Sandoz if you experience:

- signs of allergy such as skin rash, reddening, blisters or itching, swelling of the face, lips or other parts of the body, shortness of breath or wheezing.
- Pass black (blood-stained) stools

If you experience symptoms such as severe (watery or bloody) diarrhoea, fever, abdominal pain or tenderness, you may have Clostridium difficile colitis (bowel inflammation).

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.

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.

Low magnesium can lead to low calcium and/or low potassium levels in blood.

Withdrawal of long term PPI therapy may lead to worsening of acid-related symptoms.

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).

Other side effects not listed above may also occur in some people. Tell your doctor if you notice anything making you feel unwell when you are taking, or soon after you have finished taking Rabeprazole Sandoz.

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

AFTER TAKING RABEPRAZOLE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature is below 25°C. Do not keep Rabeprazole Sandoz in the refrigerator.

Do not store Rabeprazole Sandoz 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 your medicine where children cannot reach them.

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 tablets have passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Rabeprazole Sandoz comes in two types of tablets:

Rabeprazole Sandoz 10mg - pink, biconvex shaped enteric coated tablets.

Rabeprazole Sandoz 20mg - yellow, biconvex shaped enteric coated tablets.

Rabeprazole Sandoz 10mg tablets are supplied in blister packs of 28 enteric coated tablets.

Rabeprazole Sandoz 20mg are supplied in blister packs of 30 enteric coated tablets.

Ingredients

Active ingredients:

- Rabeprazole Sandoz 10mg - 10mg rabeprazole sodium
- Rabeprazole Sandoz 20mg - 20mg rabeprazole sodium

Inactive ingredients:

- calcium hydroxide
- mannitol
- hypromellose
- sodium stearyl fumarate
- hypromellose
- purified talc

- hypromellose phthalate
- dibutyl sebacate
- iron oxide yellow (10 mg & 20 mg)
- iron oxide red (10 mg only)
- titanium dioxide.

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

Supplier

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Australian Register Numbers:

10 mg enteric coated tablet: AUST R 173081 (blister)

20 mg enteric coated tablet: AUST R 173080 (blister)