

RAZIT™ 10 & 20

Rabeprazole sodium 10 mg and 20 mg enteric-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common question about RAZIT tablets. 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 RAZIT against the benefits it is expected to 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 RAZIT is used for

The name of your medicine is RAZIT. It contains the active ingredient rabeprazole sodium.

Reflux Oesophagitis:

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

Peptic Ulcers:

RAZIT is used to treat 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 RAZIT 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 RAZIT tablets are taken with antibiotics, they will help kill *Helicobacter pylori* and allow the stomach to heal.

How RAZIT works

RAZIT belongs to a group of medicines called proton pump inhibitors (PPIs). RAZIT 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.

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

Your doctor may have prescribed it for another reason.

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

Before you take RAZIT

When you must not take it:

Do not take RAZIT if you have an allergy to:

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

Symptoms of an allergic reaction may include:

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

Do not take this medicine after the expiry date printed on the pack, or if 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:

You must tell your doctor if:

- you are pregnant or intend to become pregnant;
- you are breast-feeding or intend to breast-feed. It is not known if RAZIT passes into breast milk; or

- you have or have ever had liver disease.

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 RAZIT 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; or**
- **Clopidogrel, an antiplatelet medicine.**

You should not take RAZIT while taking these medicines.

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

- Cyclosporine, a medicine used to treat several conditions including prevention of graft rejection following kidney, liver or heart transplantation; 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; or
- Clarithromycin, a medicine used to treat infections.

These medicines may be affected by RAZIT 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 RAZIT.

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

How to take it

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

They may differ from the information contained in this leaflet.

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

How much to take:

Your doctor will tell you how many tablets you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Adults

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 dose of RAZIT tablets is usually 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.

Children

RAZIT should not be given to children.

How to take it:

- RAZIT should be swallowed whole with a full 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; and
- It does not matter if you take RAZIT with food or on an empty stomach.

When to take it:

Take your 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.

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

How long to take it:

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

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 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 take too much (overdose):

Immediately telephone your doctor, or 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, if you think that you or anyone else may have taken too much RAZIT.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking it

Things you must do:

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking RAZIT, tell your doctor immediately.

Things you must not do:

- Do not use RAZIT to treat any other complaints unless your doctor tells you to;
- Do not give your medicine to anyone else, even if they have the same symptoms as you;
- Do not crush or chew the tablets; and
- Do not give RAZIT to children.

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

Things to be careful of:

Be careful driving or operating machinery until you know how RAZIT affects you.

This medicine may cause dizziness in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, symptoms such as dizziness may be worse.

Things that would be helpful for your condition:

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist for more information about these measures.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Aspirin and many other medicines used to treat arthritis/period pain/headaches** - these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.
- **Caffeine** - your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.
- **Eating habits** - eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down.
- **Weight** - your doctor may suggest losing some weight to help your condition.

Side effects

RAZIT is usually well tolerated but tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RAZIT.

RAZIT helps most people with peptic ulcers or reflux disease, but it 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 treatment if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking RAZIT, effects of your condition or side effects of other medicines you may be taking. For this reason, it is important to tell your doctor of any change in your condition.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor if you experience any of the following and they worry you:

- headache;
- diarrhoea;
- dizziness;
- abdominal pain;
- unusual weakness;
- wind;
- rash;
- dry mouth;
- dizziness;
- nausea;
- vomiting;
- constipation;
- runny nose or blocked nose;
- sore throat and discomfort when swallowing;
- cough;
- infection;
- chest pain;
- back pain;
- muscle weakness;
- insomnia;
- breast enlargement in men; or
- itchy rash accompanied by skin eruption.

These side effects are usually mild.

People who take proton pump inhibitor (PPI) 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.

Tell your doctor immediately if you notice any of the following:

- bleeding or bruising more easily than normal; or

- 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 RAZIT) or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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.

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 RAZIT.

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; or
- you pass black (blood-stained) motions.

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

Other side effects not listed above may also occur in some people.

After taking it

Storage

Keep your tablets in the pack/bottle until it is time to take them.

If you take the tablets out of the pack/bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C. Do not keep RAZIT in the refrigerator.

Do not store RAZIT, 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 it 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 tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

RAZIT 10 (10 mg) tablets are round, white, biconvex enteric-coated tablets.

RAZIT 20 (20 mg) tablets are round, yellow, biconvex enteric-coated tablets.

RAZIT tablets are supplied in blister packs of 28 (RAZIT 10) or 30 (RAZIT 20) tablets.

Ingredients

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

Each tablet also contains the following other ingredients:

- mannitol;
- heavy magnesium oxide;
- light magnesium oxide;
- magnesium stearate
- hypromellose;
- crospovidone;
- hydroxypropylcellulose;
- ethylcellulose;
- hypromellose phthalate;
- diacetylated monoglycerides;
- purified talc; and
- titanium dioxide.

RAZIT 20 mg tablets also contain:

- Iron oxide yellow (colouring).

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

Australian registration numbers

10 mg tablet (in blister packs):
AUST R 189215

20 mg tablet (in blister packs):
AUST R 189239

Sponsor/Marketing Authorisation Holder

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