

PARBEZOL 10 & 20

Rabeprazole sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PARBEZOL 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 PARBEZOL 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 PARBEZOL is used for

The name of your medicine is PARBEZOL™.

It contains the active ingredient rabeprazole sodium.

What it does

This medicine is used to treat,

- *Reflux Oesophagitis*
- *Peptic Ulcers*
- *Chronic Gastritis*

Reflux Oesophagitis:

This medicine 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:

This medicine 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 PARBEZOL 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 PARBEZOL tablets are taken with antibiotics, they will help kill *Helicobacter pylori* and allow the stomach to heal.

How it works

PARBEZOL 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.

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.

Use in Children

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

Before you take PARBEZOL™

When you must not take it

Do not take PARBEZOL if you have an allergy to:

- any medicine containing rabeprazole sodium
- any of the ingredients listed at the end of this leaflet
- other proton pump inhibitors (for example: 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 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

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 of the following medical conditions:

- liver disease

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by PARBEZOL 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 will advise you.

Do not take PARBEZOL 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 PARBEZOL while taking these medicines.

Also tell your doctor or pharmacist 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.

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

How to take PARBEZOL™

Follow all 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 PARBEZOL 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

This medicine should not be given to children.

How to take it

Swallow the tablets 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.

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. It does not matter if you take this medicine 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.

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.

This may increase your chance of getting an unwanted side effect.

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 PARBEZOL™. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using PARBEZOL™

Things you must do

Use this medicine exactly as your doctor has prescribed.

Always swallow the tablets whole.

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 treat you that you are taking this 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 this medicine, tell your doctor immediately.

Things you must not do

Do not take PARBEZOL 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 condition as you.

Do not crush or chew the tablets.

Do not give this medicine 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 PARBEZOL 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. Your doctor or pharmacist can give you 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

PARBEZOL is usually well tolerated but tell your doctor or

pharmacist as soon as possible if you do not feel well while you are taking this medicine.

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 this medicine, 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:

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

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

Also tell your doctor if your reflux/heartburn symptoms get worse.

The above list includes some of the more common side effects of your medicine.

They are usually mild and short-lived.

Tell your doctor as soon as possible if:

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

- bleeding or bruising more easily than normal
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- yellow skin
- significant mood changes
- significant weight changes
- double or blurred vision

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Go to hospital if:

Tell your doctor immediately (and do not take your next dose of PARBEZOL™) 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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.

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 using PARBEZOL™

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 store PARBEZOL™, 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 expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

PARBEZOL 10 mg tablets are round, white, enteric coated tablets.

PARBEZOL 20 mg tablets are round, yellow, enteric coated tablets.

PARBEZOL tablets are supplied in blister packs, in pack sizes of 28 tablets (10 mg) & 30 tablets (20 mg)

and HDPE plastic bottles, in pack sizes of 90 tablets (20 mg).

Ingredients

Each PARBEZOL 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
- diacetylatedmonoglycerides
- purified talc
- titanium dioxide

PARBEZOL 20 mg tablets also contain:

- - Iron oxide yellow (colouring)

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

Sponsor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

Australian registration numbers

10 mg tablet (in blister packs):

AUST R 216107

20 mg tablet (in blister packs):

AUST R 216109

20 mg tablet (in HDPE bottles):

AUST R 216110

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