

PRABEZ Tablets

Rabeprazole sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PRABEZ 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 PRABEZ against the benefits this medicine is expected to have for you.

If you have any concerns about using PRABEZ ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What PRABEZ is used for

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

Reflux Oesophagitis:

PRABEZ 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.

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

Peptic Ulcers:

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

How PRABEZ works

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

Your doctor may have prescribed PRABEZ for another reason. Ask

your doctor if you have any questions about why PRABEZ has been prescribed for you.

PRABEZ is only available with a doctor's prescription.

Before you take PRABEZ

When you must not take it

Do not take PRABEZ 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:

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

Do not take PRABEZ if:

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

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 PRABEZ passes into breast milk.

- 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 PRABEZ 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 PRABEZ 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.

These medicines may be affected by PRABEZ or may affect how well PRABEZ 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 PRABEZ.

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

Taking PRABEZ

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

How much to take:

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 PRABEZ 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

PRABEZ should not be given to children.

How to take it:

- PRABEZ 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 PRABEZ 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 you missed.

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

If you have trouble remembering when 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 for advice, or go to Accident and Emergency at your nearest hospital.

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

Poisons Information Centre telephone numbers:

- Australia: 13 11 26

While you are using PRABEZ

Things you must do

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

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

Things you must not do

- **Do not use PRABEZ to treat any other complaint unless your doctor says so.**
- **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 PRABEZ to children.**

Things that may help 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

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

PRABEZ 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 side effects.

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
- abdominal pain
- unusual weakness
- wind
- rash
- dry mouth
- dizziness
- 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
- 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
- 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 PRABEZ 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.

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 PRABEZ.

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.

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

After using PRABEZ

Storage

Do not take PRABEZ tablets out of the blister pack until it is time to take them. If you take them out of the blister they may not keep well.

Keep PRABEZ tablets in a cool dry place where the temperature is below 25°C. Do not keep PRABEZ in the refrigerator.

Do not store PRABEZ, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your medicines where children cannot reach them. A

locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking PRABEZ tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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30-34 Hickson Road
Millers Point NSW 2000
Phone: (02) 9298 3999
www.alphapharm.com.au

Australian registration numbers:

- AUST R 196564
- AUST R 196572

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Product description

What it looks like

PRABEZ 10 mg tablets are pink, round, biconvex coated tablets and plain on both sides.

This is available in a blister pack of 28 tablets.

PRABEZ 20 mg tablets are light yellow, round, biconvex coated tablets and plain on both sides.

This is available in a blister pack of 30 tablets.

Ingredients

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

Each tablet also contains the following other ingredients:

- mannitol, light magnesium oxide, hypromellose, magnesium stearate, ethylcellulose, hypromellose phthalate, diacetylated monoglycerides, purified talc, titanium dioxide and carnauba wax
- The 20 mg tablets also contain iron oxide yellow
- The 10 mg tablets contain iron oxide red
- The tablets do not contain lactose or gluten.

Sponsor

Alphapharm Pty Limited
(ABN 93 002 359 739)