

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZABEP?

ZABEP contains the active ingredient rabeprazole sodium. ZABEP is used to treat gastro-oesophageal reflux disease, peptic ulcers, and chronic gastritis in adults. For more information, see Section [1. Why am I using ZABEP?](#) in the full CMI.

2. What should I know before I use ZABEP?

Do not use if you have ever had an allergic reaction to rabeprazole sodium or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ZABEP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZABEP and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZABEP?

- Use ZABEP exactly as your doctor has prescribed. The dose of ZABEP 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.
- The usual dose is one tablet, to be taken once daily at the same time each day. Always swallow ZABEP tablets whole.

More instructions can be found in Section [4. How do I use ZABEP?](#) in the full CMI.

5. What should I know while using ZABEP?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using rabeprazole sodium.• Use ZABEP exactly as your doctor has prescribed.• Tell your doctor if you need to have a specific blood test (Chromogranin A) while you are taking ZABEP
Things you should not do	<ul style="list-style-type: none">• Do not give this medicine to anyone else, even if they have the same symptoms as you.• Do not crush or chew the tablets.
Driving or using machines	<ul style="list-style-type: none">• Make sure you know how you react to ZABEP before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.
Looking after your medicine	<ul style="list-style-type: none">• Keep ZABEP tablets in a cool dry place where the temperature is below 25°C.• Do not take ZABEP tablets out of the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using ZABEP?](#) in the full CMI.

6. Are there any side effects?

ZABEP is usually well tolerated but tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZABEP. The common side effects include headache, dizziness, diarrhoea, nausea, abdominal pain, wind, vomiting, constipation, runny or blocked nose, sore throat, cough, non-specific pain, back pain, muscle pain, rash, muscle weakness, physical weakness or lack of energy, flu-like syndrome, infection, insomnia, and chest pain. The serious side effects include allergic reactions; frequent infections; urinary tract infection, vision or taste disturbance, depression, feeling dizzy, faint, lightheaded or weak (hypotension), pain or indigestion, begin to vomit blood or food, pass black (blood-stained) stools, symptoms of bowel inflammation such as severe (watery or bloody) diarrhoea, fever, abdominal pain or tenderness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZABEP®

Active ingredient(s): *rabeprazole sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZABEP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZABEP.**

Where to find information in this leaflet:

- [1. Why am I using ZABEP?](#)
- [2. What should I know before I use ZABEP?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZABEP?](#)
- [5. What should I know while using ZABEP?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZABEP?

ZABEP contains the active ingredient rabeprazole sodium. ZABEP belongs to a group of medicines called proton pump inhibitors (PPIs). ZABEP 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 same way.

ZABEP is used to treat:

- **Gastro-oesophageal reflux disease:**

ZABEP is used to treat gastro-oesophageal reflux disease (GORD), commonly known as 'reflux'. 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. ZABEP is also used to help stop gastro-oesophageal reflux disease from coming back or relapsing.

- **Peptic Ulcers:**

ZABEP 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 bacteria called *Helicobacter pylori* in their stomach. Your doctor may also prescribe a course of antibiotics (clarithromycin and amoxicillin) for you. When ZABEP 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 ZABEP tablets are taken with antibiotics, they will help kill *Helicobacter pylori* and allow the stomach to heal.

Your doctor may have prescribed ZABEP for another reason. Ask your doctor if you have any questions about why ZABEP has been prescribed for you.

2. What should I know before I use ZABEP?

Warnings

Do not use ZABEP if:

- you are allergic to rabeprazole sodium, other PPIs (omeprazole, esomeprazole, lansoprazole, pantoprazole), or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have now, or have had in the past, liver problems
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if ZABEP passes into breast milk.

Children and adolescents

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

3. What if I am taking other medicines?

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

Some medicines may interfere with ZABEP and affect how it works. These include:

Do not take ZABEP 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 ZABEP 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.
- mycophenolate mofetil, a medicine used to prevent organ rejection following kidney, liver or heart transplants.
- clarithromycin, a medicine used to treat infections.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZABEP.

4. How do I use ZABEP?

How much to take / use

- The usual dose is one tablet to be taken once daily.
- The dose of ZABEP 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.
- For treating *Helicobacter pylori* infections in combination with antibiotics (clarithromycin and amoxicillin), the usual dose is one 20mg tablet twice daily, morning and evening, for 7 days.
- Follow the instructions provided and use ZABEP until your doctor tells you to stop.

When to take / use ZABEP

- ZABEP should be taken at the same time each day.

How to take ZABEP

- ZABEP 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 ZABEP with food or on an empty stomach

If you forget to use ZABEP

If you miss your dose at the usual time, take it as soon as you remember and then continue to take it as you would normally.

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 use too much ZABEP

If you think that you have used too much ZABEP, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ZABEP?

Things you should do

- Use ZABEP exactly as your doctor has prescribed.
- **Tell your doctor if you need to have a specific blood test (Chromogranin A) while you are taking ZABEP.** It may affect the results of this test.

Call your doctor straight away if you:

- become pregnant while you are taking ZABEP

Remind any doctor, dentist or pharmacist you visit that you are using ZABEP.

Things you should not do

- Do not use ZABEP to treat any other complaints unless your doctor says 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 ZABEP to children.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZABEP affects you.

ZABEP may cause dizziness in some people.

Looking after your medicine

- Do not take ZABEP tablets out of the blister pack until it is time to take them. ZABEP tablets are packaged in a double-sided aluminium blister strip. If you take them out of the blister they may not keep well.
- Keep ZABEP tablets in a cool dry place where the temperature is below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Brain or nervous system related:</p> <ul style="list-style-type: none"> headache sleeplessness (insomnia) sleepiness (somnolence) nervousness <p>Stomach or bowel related:</p> <ul style="list-style-type: none"> nausea vomiting stomach pain belching or indigestion wind diarrhoea constipation <p>Skin related:</p> <ul style="list-style-type: none"> rash or itchy rash accompanied by skin eruptions or blisters <p>Muscle or joint related:</p> <ul style="list-style-type: none"> pain (including back or joint pain) leg cramps muscle weakness, physical weakness or lack of energy <p>Breathing related:</p> <ul style="list-style-type: none"> cough flu-like symptoms runny or blocked nose sore throat and discomfort when swallowing <p>Other:</p> <ul style="list-style-type: none"> dry mouth swelling of the arms or legs loss of appetite for food (anorexia) weight gain sweating 	<p>Speak to your doctor if you have any of these less serious side effects.</p>

Less serious side effects	What to do
<p>Long-term use related (when PPIs might be used for long periods of time under rare circumstances supervised by the doctor):</p> <ul style="list-style-type: none"> Low magnesium can occur in some people who take a PPI. 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. PPIs 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 PPI for a long time (i.e. more than 3 years). People who take 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. Withdrawal of long-term PPI therapy may lead to worsening of acid-related symptoms. 	<p>Speak to your doctor if you have any of these less serious side effects.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reactions:</p> <ul style="list-style-type: none"> skin rash, reddening, blisters or itching on the skin shortness of breath or wheezing swelling of the face, lips or other parts of the body <p>Infection related:</p> <ul style="list-style-type: none"> signs of frequent infections such as fever, chills, sore throat or mouth ulcers common symptoms of a urinary tract infection such as painful and/or frequent urination <p>Brain or nervous system related:</p> <ul style="list-style-type: none"> vision or taste disturbance depression feeling dizzy, faint, lightheaded or weak (hypotension) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Heart related:</p> <ul style="list-style-type: none"> chest pain <p>Stomach or bowel related:</p> <ul style="list-style-type: none"> pain or indigestion that may be related to the ulcer itself begin to vomit blood or food pass black (blood-stained) stools symptoms of Clostridium difficile colitis (bowel inflammation) such as severe (watery or bloody) diarrhoea, fever, abdominal pain or tenderness 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people and are more likely to arise from the ulcer itself rather than the treatment.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ZABEP contains

Active ingredient (main ingredient)	rabeprazole sodium
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> povidone, mannitol, light magnesium oxide, hydroxypropyl cellulose, magnesium stearate, ethylcellulose, methylacrylic acid-ethyl acrylate copolymer (1:1), polysorbate 80, sodium lauryl sulfate, propylene glycol, purified talc, iron oxide yellow titanium dioxide)

Do not take this medicine if you are allergic to any of these ingredients.

What ZABEP looks like

ZABEP 20 is a yellow elliptical biconvex tablet with no markings (AUST R 191867)

ZABEP 20 tablets are available in blister packs of 30 tablets.

Who distributes ZABEP

Sponsor

Medis Pharma Pty Ltd

Distributor

ZABEP is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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