

# RABEPRAZOLE VIATRIS

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## 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 RABEPRAZOLE VIATRIS?

RABEPRAZOLE VIATRIS contains the active ingredient rabeprazole sodium. RABEPRAZOLE VIATRIS is used to treat gastro oesophageal reflux disease (GORD). For more information, see Section [1. Why am I using RABEPRAZOLE VIATRIS?](#) in the full CMI.

### 2. What should I know before I use RABEPRAZOLE VIATRIS?

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 RABEPRAZOLE VIATRIS?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with RABEPRAZOLE VIATRIS 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 RABEPRAZOLE VIATRIS?

RABEPRAZOLE VIATRIS 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 VIATRIS with food or on an empty stomach. More instructions can be found in Section [4. How do I use RABEPRAZOLE VIATRIS?](#) in the full CMI.

### 5. What should I know while using RABEPRAZOLE VIATRIS?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using RABEPRAZOLE VIATRIS.

	<ul style="list-style-type: none"> <li>● Use RABEPRAZOLE VIATRIS exactly as your doctor has prescribed.</li> <li>● Always swallow RABEPRAZOLE VIATRIS tablets whole.</li> <li>● Tell your doctor if you become pregnant while you are taking RABEPRAZOLE VIATRIS.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Remind any doctor, dentist or pharmacist you visit that you are using RABEPRAZOLE VIATRIS.</li> <li>● Use RABEPRAZOLE VIATRIS exactly as your doctor has prescribed.</li> <li>● Always swallow RABEPRAZOLE VIATRIS tablets whole.</li> <li>● Tell your doctor if you become pregnant while you are taking RABEPRAZOLE VIATRIS.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful when drinking alcohol. Your doctor may advise you to limit</li> </ul>

	your alcohol intake when taking this medication.
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store below 25°C.</li> </ul>

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

## 6. Are there any side effects?

Common side effects: headache, dizziness, diarrhoea, nausea, abdominal pain, wind, vomiting, constipation, indigestion, belching, runny or blocked nose, sore throat and discomfort when swallowing, cough, chest pain, back pain, joint pain, muscle weakness, physical weakness or lack of energy, rash, 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, infection and breast enlargement in men.

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.

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.



# RABEPRAZOLE VIATRIS

Active ingredient(s): *rabeprazole sodium*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using RABEPRAZOLE VIATRIS. **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 RABEPRAZOLE VIATRIS.**

Where to find information in this leaflet:

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

## 1. Why am I using RABEPRAZOLE VIATRIS?

RABEPRAZOLE VIATRIS contains the active ingredient **rabeprazole sodium**. RABEPRAZOLE VIATRIS is a proton pump inhibitor (PPI). It works by

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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.

**RABEPRAZOLE VIATRIS is used to treat gastro# oesophageal reflux disease (GORD), gastric and duodenal ulcers and chronic gastritis.**

## **2. What should I know before I use RABEPRAZOLE VIATRIS?**

### **Warnings**

#### **Do not use RABEPRAZOLE VIATRIS if:**

- you are allergic to rabeprazole sodium, or any of the ingredients listed at the end of this leaflet.
- you are allergic to other proton pump inhibitors (omeprazole, esomeprazole, lansoprazole, pantoprazole). Always check the ingredients to make sure you can use this medicine.
- you are under 18 years of age. Safety and effectiveness of RABEPRAZOLE VIATRIS in children has not been established.

#### **Check with your doctor if you:**

- have or have ever had liver disease
- 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 RABEPRAZOLE VIATRIS passes into breast milk.

## **Children**

RABEPRAZOLE VIATRIS should not be given to children under 18 years of age. Safety and effectiveness of RABEPRAZOLE VIATRIS 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 RABEPRAZOLE VIATRIS and affect how it works e.g.**

- 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

These medicines may be affected by RABEPRAZOLE VIATRIS 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 VIATRIS. Your doctor will advise you whether or not to take RABEPRAZOLE VIATRIS or if you need to have your dose adjusted.

**Do not take RABEPRAZOLE VIATRIS 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.

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

## **4. How do I use RABEPRAZOLE VIATRIS?**

### **How much to take / use**

#### **Adults**

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

#### **Helicobacter pylori infections**

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

### **How to take RABEPRAZOLE VIATRIS**

- RABEPRAZOLE VIATRIS 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 VIATRIS with food

## **If you forget to use RABEPRAZOLE VIATRIS**

RABEPRAZOLE VIATRIS should be used regularly at the same time each day. 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.**

- [include explanation of what “almost time for your next dose” refers to for the specific medicine where possible e.g. oral contraceptives]
- [include any other medicine-specific action and advice about missed dose, as appropriate]

## **If you use too much RABEPRAZOLE VIATRIS**

If you think that you have used too much RABEPRAZOLE VIATRIS, 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 RABEPRAZOLE VIATRIS?**

### **Things you should do**

#### **Call your doctor straight away if you:**

- notice anything making you feel unwell when you are taking, or soon after you have finished taking RABEPRAZOLE VIATRIS. 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. 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).

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.

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 VIATRIS.

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

## **Things you should not do**

Do not take this medicine if:

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

## **Things to be careful of**

- 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.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how RABEPRAZOLE VIATRIS affects you.**

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

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

Your doctor may advise you to limit your alcohol intake.

## **Looking after your medicine**

- Keep your medicine in the original container. If you take it out of its original container it may not keep well.

- Store below 25°C. Do not keep RABEPRAZOLE VIATRIS in the refrigerator.

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.**

## **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
<ul style="list-style-type: none"><li>● headache</li><li>● dizziness</li><li>● diarrhoea</li><li>● nausea</li><li>● abdominal pain</li><li>● wind</li><li>● vomiting</li><li>● constipation</li><li>● indigestion</li><li>● belching</li><li>● runny or blocked nose</li><li>● sore throat and discomfort when swallowing</li><li>● cough</li><li>● chest pain</li><li>● back pain</li><li>● joint pain</li><li>● muscle weakness, physical weakness or lack of energy</li><li>● rash</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● itchy rash accompanied by skin eruption or blisters</li> <li>● flu-like symptoms</li> <li>● sleeplessness (insomnia)</li> <li>● dry mouth</li> <li>● leg cramps</li> <li>● swelling of the arms or legs</li> <li>● nervousness</li> <li>● sleepiness (somnolence)</li> <li>● loss of appetite for food (anorexia)</li> <li>● weight gain</li> <li>● sweating</li> <li>● infection</li> <li>● breast enlargement in men</li> </ul>	

### **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● painful and/or frequent urination (common</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>symptoms of a urinary tract infection)</p> <ul style="list-style-type: none"> <li>● vision or taste disturbance</li> <li>● depression</li> <li>● feeling dizzy, faint, lightheaded or weak (hypotension)</li> <li>● shortness of breath</li> <li>● bleeding or bruising more easily than normal</li> <li>● signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>● 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</li> <li>● pain or indigestion</li> <li>● vomiting blood or food</li> <li>● passing black (blood stained) motions</li> </ul>	<p><b>Department at your nearest hospital if you notice any of these serious side effects.</b></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.

## 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](http://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 RABEPRAZOLE VIATRIS contains

<b>Active ingredient (main ingredient)</b>	Rabeprazole sodium
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● Light Magnesium oxide</li><li>● mannitol</li><li>● hypromellose</li><li>● sodium starch glycollate</li><li>● hypromellose</li></ul>

- magnesium stearate
- ethyl cellulose
- diethyl phthalate
- titanium dioxide
- hypromellose phthalate
- iron oxide - yellow (20 mg)
- iron oxide - red (10 mg)

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

## **What RABEPRAZOLE VIATRIS looks like**

RABEPRAZOLE VIATRIS 10mg - red biconvex enteric coated tablets, plain on both sides. RABEPRAZOLE VIATRIS 10mg tablets are supplied in blister packs of 28 enteric coated tablets (AUST R 189752).

RABEPRAZOLE VIATRIS 20mg - yellow biconvex enteric coated tablets, plain on both sides. RABEPRAZOLE VIATRIS 20mg are supplied in blister packs of 30 enteric coated tablets (AUST R 189753).

## **Who distributes RABEPRAZOLE VIATRIS**

### **Sponsor**

Helix Pharmaceuticals Pty Ltd

C/-EGA Corporate Advisers Pty Ltd

Level 12, 468 St Kilda Rd

Melbourne VIC 3004

Contact: [info@helixpharmaceuticals.com.au](mailto:info@helixpharmaceuticals.com.au)

**Distributor**

RABEPRAZOLE VIATRIS 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](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in March 2026.