

Rabeprazole 10 mg gastro-resistant tablets

Rabeprazole 20 mg gastro-resistant tablets

rabeprazole sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Rabeprazole is and what it is used for

Rabeprazole contains rabeprazole which belongs to a group of drugs called proton pump inhibitors.

Rabeprazole works by reducing the production of gastric acid. This prevents irritation of the stomach's mucosa, so that the gastric ulcer can heal. This relieves pain and discomfort caused by ulcers.

Rabeprazole is used for:

- duodenal ulcers
- benign gastric ulcers
- pain or discomfort caused by gastric acid that flows back into the oesophagus (the tube from the mouth to the stomach). This action can irritate the oesophagus, causing heartburn and other symptoms.
- once the symptoms disappear, Rabeprazole may also be used to prevent the recurrence of the disease
- elimination of *Helicobacter pylori* (bacteria that infects the stomach) in patients with benign gastric ulcers (peptic ulcers) in combination with antibiotics
- Zollinger-Ellison Syndrome (disorder that causes tumors in the pancreas and duodenum and ulcers in the stomach and duodenum)

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Rabeprazole

Do not take Rabeprazole:

- if you are allergic to rabeprazole or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant, planning to become pregnant or breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rabeprazole.

- if you are allergic to other proton pump inhibitors or 'substituted benzimidazoles' (e.g. pantoprazole, lansoprazole, omeprazole, esomeprazole)
- if you have severe liver disease
- if you are taking a medicine called atazanavir (used to treat HIV; see section 2, Other medicines and Rabeprazole)
- if you are taking an immunosuppressant medicine called methotrexate, (see section 2, Other medicines and Rabeprazole)
- if you have a tumour in the stomach or food pipe. Your doctor may carry out certain tests to rule out cancer before starting the treatment with rabeprazole.
- if you are on long term treatment with rabeprazole and are also taking medicines like digoxin (used to treat heart problems) or water tablets such as furosemide, spironolactone, hydrochlorothiazides (used to treat high blood pressure or heart problems). Your doctor may carry out frequent check-ups during treatment with rabeprazole in such cases.
- if you have reduced body stores or risk factors for reduced vitamin B₁₂ and receive rabeprazole long-term treatment. As with all acid reducing agents, rabeprazole may lead to a reduced absorption of vitamin B₁₂.
- if you have ever had a skin reaction after treatment with a medicine similar to Rabeprazole that reduces stomach acid.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Rabeprazole. Remember to also mention any other ill-effects like pain in your joints.

During treatment

Talk to your doctor or pharmacist if:

- you experience severe or persistent diarrhoea (watery or bloody) with symptoms such as fever, abdominal pain or tenderness, as rabeprazole has been associated with a small increase in infectious diarrhoea.
- you suffer from a reduction in certain type of blood cells with symptoms such more frequent infections (such as sore throat and mouth ulcers) and fever, easy bruising or bleeding.

Taking a proton pump inhibitor like Rabeprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip,

wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

If you are on long-term treatment (particularly if treated for more than 1 year) with Rabeprazole. You should be regularly checked.

Children

The use of Rabeprazole in children is not recommended.

Other medicines and Rabeprazole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Rabeprazole can interact with certain other medicines such as the following:

- ketoconazole or itraconazole (medicines used to treat fungal diseases)
- atazanavir (a medicine used to treat HIV)
- methotrexate (a chemotherapy medicine used in high doses to treat cancer and inflammatory conditions) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your rabeprazole treatment.

If you are taking any of the above, your dose may need adjustment.

Pregnancy, breast-feeding and fertility

Do not take Rabeprazole if you are pregnant, planning to become pregnant or breast-feeding.

Driving and using machines

It is unlikely that Rabeprazole would cause impairment in driving or ability to use machines. If you feel drowsy, do not drive or use machines.

3. How to take Rabeprazole

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

Rabeprazole gastro-resistant tablets must not be chewed, divided or crushed. They are to be swallowed whole with some water.

When administering Rabeprazole once daily, it should preferably be taken in the morning before breakfast.

Dosage:

- *For duodenal ulcers or benign gastric ulcers:* the recommended dose is 20 mg once daily.
- *For pain or discomfort caused by gastric acid that flows back into the oesophagus (the tube from the mouth to the stomach). This action can irritate the oesophagus causing heartburn and other symptoms. Sometimes there will be an active ulcer in addition sometimes there will be no active ulcer.*
When there is an active ulcer: the recommended dose is 20 mg once daily for 4-8 weeks.
When there is no active ulcer: the recommended dose is 10 mg once daily. If the symptoms continue after four weeks your doctor may carry out certain tests. Once the symptoms are gone, any reappearing symptoms may be controlled by taking 10 mg once daily as needed.
- *To prevent the recurrence of the disease:* your doctor will prescribe 10 mg or 20 mg once daily depending on your personal need.
- *For eliminating Helicobacter pylori (bacteria that infects the stomach):* the following treatment is frequently recommended for 7 days: Rabeprazole 20 mg twice daily + clarithromycin 500 mg twice daily and amoxicillin 1 g twice daily.
- *For Zollinger-Ellison syndrome:* the recommended dose is 60 mg once daily. The dose may be increased to 60 mg twice daily. Single daily doses up to 100mg/day may be given.

Duration of treatment:

- *For duodenal ulcers:* Usually for 4 weeks, but afterwards your doctor may decide to continue the treatment for another 4 weeks.
- *For benign gastric ulcers:* Usually for 6 weeks, but afterwards your doctor may decide to continue the treatment for another 6 weeks.
- *For pain or discomfort caused by gastric acid that flows back into the oesophagus with an active ulcer:* 4 – 8 weeks.



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MA No.	PA 577/179/001 PA 577/179/002	Glams Proof No.	N/A	Main Font	Times New Roman	Body Text Size	10 pt
Packing Site/Printer	Laboratorios Liconsa	Client Market	Ireland	Dimensions	140 x 540 mm	Min Text Size used	10 pt
Supplier Code	N/A	Keyline/Drawing No.	N/A				
		Barcode Info	N/A				
Sign-offs							

