Package leaflet: information for the user

Rabeprazole 10 mg gastro-resistant tablets
Rabeprazole 20 mg gastro-resistant tablets

rabeprazole sodium

Read all of this leaflet carefully before you start using 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

1. What Rabeprazole is and what it is used for

Rabeprazole belongs to a group of medicines called "proton pump inhibitors". These medicines reduce the production of acid in your stomach.

Rabeprazole is used for treating the following conditions in adults:

- ulcers in the gut (also called duodenal ulcer)
- ulcers in the stomach (also called benign gastric ulcer)
- relieving the symptoms of heartburn caused by erosive or ulcerative gastro-oesophageal reflux disease (GORD) which is also called reflux oesophagitis
- long-term treatment of GORD to prevent it re-occurring
- relieving the symptoms of moderate to very severe GORD (symptomatic GORD) like heartburn and acid regurgitation
- severely increased acid secretion in the stomach (Zollinger-Ellison syndrome)
- treatment of infections caused by bacteria called *Helicobacter pylori* (*H pylori*) when given in combination with antibiotic therapy.

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)
- pregnant or think that you are pregnant
- breast-feeding.

Do not use Rabeprazole if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Rabeprazole.

Warnings and precautions
Talk to your doctor or pharmacist before taking Rabeprazole:
- If you are allergic to other proton pump inhibitors or 'substituted benzimidazoles'.
- If you have a stomach tumour.
- If you are on long-term treatment (longer than one year) you need to see your doctor at regular intervals.
- If you have or had liver problems, you must tell your doctor. Your doctor may check your liver function more often.
- If you are taking atazanavir (a medicine used to treat HIV) with these tablets is not recommended (see section 2).
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B12.
- If you are due to have a specific blood test (Chromogranin A).
- 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.

If you experience severe (watery or bloody) diarrhoea with symptoms such as fever, abdominal pain or tenderness, stop taking Rabeprazole and see a doctor straight away.

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).

Children
Rabeprazole should not be used in children.

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

Talk to your doctor before taking these tablets if you are already taking:
- ketoconazole or itraconazole (medicines used to treat fungal infections) – your dose may need to be adjusted
- atazanavir (a medicine used to treat HIV). Rabeprazole may lower the amount of this type of medicine in your blood and they should not be used together.
- methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Rabeprazole treatment.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Rabeprazole.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. Ask your doctor or pharmacist for advice before taking any medicine. Do not take these tablets if you are pregnant or are breast-feeding.

Driving and using machines

Usually Rabeprazole does not affect the ability to drive and use machines. However, this medicine may cause some patients to become sleepy. If you experience this side effect, you should not drive or operate machinery.

3. How to take Rabeprazole

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

If you are taking Rabeprazole once a day, take the tablet before eating in morning.
Swallow the tablets whole. Do not crush or chew the tablets.

Ulcers in the gut (duodenal ulcer)
The usual dose is 20 mg once daily in the morning for 4 weeks. Your doctor may decide to prolong the treatment for another 4 weeks.

Ulcers in the stomach
The usual dose is 20 mg once daily in the morning for 6 weeks. Your doctor may decide to prolong the treatment for another 6 weeks.

Erosive or ulcerative gastro-oesophageal reflux disease (GORD)
The usual dose is 20 mg once daily for 4-8 weeks.

Long-term treatment of gastro-oesophageal reflux disease (GORD)
The usual maintenance dose is 10 mg or 20 mg once daily. If you are on long-term treatment you must see your doctor at regular intervals for review of your tablets and symptoms.

Relieving the symptoms of moderate to very severe gastro-oesophageal reflux disease (GORD)
The usual dose is 10 mg once daily for 4 weeks.
If your symptoms do not resolve within 4 weeks consult your doctor. Following this initial 4 week treatment, if your symptoms return, your doctor may then tell you to take one 10 mg tablet when needed in order to control your symptoms.

Severely increased acid secretion in the stomach (Zollinger-Ellison syndrome)
The usual starting dose is 60 mg once daily. The dose may then be adjusted by your doctor depending on how you respond to the treatment. Doses up to 60 mg twice daily may be given to you. Your doctor will tell you how many tablets to take, when to take them and how long to take them.

Treatment of infections caused by *H. pylori* when given in combination with antibiotic therapy
The usual dose is 20 mg twice daily in combination with two antibiotics. The recommended combination is:
Rabeprazole 20 mg + clarithromycin 500 mg + amoxicillin 1 g, taken together twice daily for 7 days.

Renal and hepatic impairment
Dose adjustment is not necessary.

Use in children
Do not give these tablets to children.

If you take more Rabeprazole than you should

If you accidentally take more tablets than the prescribed dose, contact your doctor or nearest hospital casualty department. Take this leaflet, any remaining tablets and the container with you to the doctor or hospital so that they know what tablets were taken.

If you forget to take Rabeprazole
It is important to take your medicine every day as regular treatment is more effective. However, if you forget to take one or more doses, take another as soon as you remember and then go on as prescribed. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking Rabeprazole
Relief of symptoms will normally occur before the ulcer has completely healed. **It is important that you do not stop taking the tablets until told to do so by your doctor.**

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
You should contact your doctor **immediately** if you notice any of the following **serious side effects** (it may be **an allergic reaction**):

Rare serious side effects (**may affect up to 1 in 1,000 people**)
- swelling of the face, lips, tongue and throat which may cause difficulty in breathing, speaking or swallowing, a sharp drop in blood pressure, pallor, fainting or collapse.

Very rare serious side effects (**may affect up to 1 in 10,000 people**)
- blistering of the skin, and/or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (Steven-Johnson syndrome) or peeling of the skin (toxic epidermal necrolysis).

Other possible side effects
Common side effects (may affect up to 1 in 10 people) are:
- headache, dizziness
- inability to sleep
- cough, sore throat, runny and stuffy nose
- diarrhoea, vomiting, feeling sick, stomach ache, constipation, wind (flatulence)
- non-specific pain, back pain
- infection
- weakness, flu like illness
- benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people) are:
- nervousness, drowsiness
- cough with phlegm, chest pain and fever
- feeling of pressure or pain in the cheeks and forehead
- indigestion, dry mouth, belching
- rash, skin reddening
- muscle pain, leg cramps, joint pain
- urinary tract infection
- chest pain, chills, fever
- increased liver enzymes

- fracture of the hip, wrist or spine.

Rare side effects (may affect up to 1 in 1,000 people) are:
- blood disorders which may lead to frequent infections, bleeding or bruising more easily than normal or tiredness
- loss of appetite (anorexia)
- vision disturbances
- gastritis, which might cause stomach pain and nausea
- sore mouth
- taste disturbances
- liver disorder (hepatitis) which may make your skin or whites of the eyes yellow (jaundice)
- liver failure leading to brain damage in patients who have previously had liver disease
- itching and skin blisters: these usually disappear on stopping treatment
- sweating
- kidney problems which might cause high or low urine output
- weight gain
- depression
- hypersensitivity (includes allergic reactions).

Not known (frequency cannot be estimated from the available data)
- low sodium levels in the blood
- low magnesium levels in the blood*
- confusion
- breast enlargement in men
- swelling of the ankles, feet or fingers
- rash, possibly with pain in the joints
- inflammation of the gut (leading to diarrhoea).

* If you are on Rabeprazole for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rabeprazole

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the tablet blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rabeprazole contains
The active substance is rabeprazole sodium.
Each 10 mg gastro-resistant tablet contains 10 mg rabeprazole sodium.
Each 20 mg gastro-resistant tablet contains 20 mg rabeprazole sodium.

The other ingredients are:
Tablet core: Calcium hydroxide, mannitol, low-substituted hydroxypropyl cellulose and sodium stearyl fumarate.
Coating 1: Hypromellose, talc
Gastro-resistant coating 2 (10mg): Hypromellose phthalate, dibutyl sebacate, yellow ferric oxide (E172), red ferric oxide (E172) and titanium dioxide (E171)
Gastro-resistant coating 2 (20mg): Hypromellose phthalate, dibutyl sebacate, yellow ferric oxide (E172) and titanium dioxide (E171)

What Rabeprazole looks like and contents of the pack
Rabeprazole 10 mg is a pink, round, biconvex, film-coated gastro-resistant tablet.

Rabeprazole 20 mg is a yellow, round, biconvex, film-coated gastro-resistant tablet.

Al/Al blister with a desiccant:

7, 10, 14, 20, 28, 30, 56, 60 and 98 gastro-resistant tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.
Salutas Pharma GmbH, Dieselstrasse 5, 70839 Gerlingen, Germany.
Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Rabeprazol Hexal 10 mg - magensaftresistente Tabletten
	Rabeprazol Hexal 20 mg - magensaftresistente Tabletten
Ireland	Rabeprazole 10mg Gastro-resistant tablets
	Rabeprazole 20mg Gastro-resistant tablets
Italy	RABEPRAZOLO Sandoz 10 mg compresse gastroresistenti
	RABEPRAZOLO Sandoz 20 mg compresse gastroresistenti

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