Package leaflet: Information for the patient

Rabeprazole Sodium 10 mg Gastro-resistant Tablets
Rabeprazole Sodium 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rabeprazole Sodium is and what it is used for

Rabeprazole Sodium belongs to a group of medicines called Proton Pump Inhibitors (PPIs).
Rabeprazole Sodium acts by reducing the amount of acid made by the stomach.

Rabeprazole Sodium is used to treat:
- ulcer in the upper part of the intestine (duodenal ulcer) and benign stomach ulcer.
- gastro-oesophageal reflux disease (GORD) with or without ulcer. GORD is commonly referred to as inflammation of the gullet caused by acid and associated with heartburn. Heartburn is a burning feeling rising from the stomach or lower chest up towards the neck. Rabeprazole Sodium may be used as a long term treatment of GORD (GORD maintenance). Rabeprazole Sodium may also be used for the symptomatic treatment of moderate to very severe gastro-oesophageal reflux disease (symptomatic GORD).
- Zollinger-Ellison Syndrome, which is a condition when the stomach makes extremely high amounts of acid.

In combination with two antibiotics (clarithromycin and amoxicillin) Rabeprazole Sodium is used for the eradication of *H pylori* infection in patients with peptic ulcer disease. For further information on the antibiotics used in the *H pylori* eradication therapy see the individual patient information leaflets.

2. What you need to know before you take Rabeprazole Sodium

Do not take Rabeprazole Sodium
- if you are allergic (hypersensitive) to rabeprazole sodium or any of the other ingredients of this medicine (listed in section 6)
- if you are **pregnant** or think that you are pregnant
- if you are **breast feeding**.

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

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Rabeprazole Sodium

- if you are **allergic** to other proton pump inhibitors or "substituted benzimidazoles".
- if you have a stomach tumour.
- if you have or have had any **liver problems**.
- if you are taking a medicine called **atazanavir** (used to treat HIV).
- 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 have ever had a skin reaction after treatment with a medicine similar to Rabeprazole Sodium that reduces stomach acid.
- if you are due to have a specific blood test (Chromogranin A).

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 Sodium. Remember to also mention any other ill-effects like pain in your joints.

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

Your doctor may perform or have performed an additional investigation called an endoscopy in order to diagnose your condition and/or exclude malignant disease. The possibility of stomach and oesophageal tumours should be excluded before the treatment is started.

If you take Rabeprazole Sodium on a long-term basis (longer than one year) your doctor will probably monitor you regularly. You should report any new or different symptoms whenever you see your doctor.

Taking a proton pump inhibitor like Rabeprazole Sodium, especially over a period of more than one year, may slightly increase your risk of fracture of 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).

Talk to your doctor straight away if you experience severe (watery or bloody) or persistent diarrhoea with symptoms such as fever, abdominal pain or tenderness, as rabeprazole has been associated with a small increase in infectious diarrhoea.

Some abnormal blood and liver enzyme values have been reported during treatment with Rabeprazole Sodium. Usually, the values become normal when the treatment is discontinued.

Children
Rabeprazole Sodium are not recommended for use in children.

Other medicines and Rabeprazole Sodium
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is especially important in case you are taking any of the following medicines:

- **atazanavir** (used to treat HIV); Rabeprazole Sodium may lower the amount of this type of medicine in your blood and they should not be used together.
- **ketoconazole or itraconazole** (used to treat infections caused by a fungus). Rabeprazole Sodium may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
- **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 Sodium 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
Do not use Rabeprazole Sodium if you are pregnant or think you may be pregnant.
Do not use Rabeprazole Sodium if you are breast-feeding or planning to breast-feed.

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 this medicine.

Driving and using machines
Occasionally rabeprazole can cause sleepiness. Therefore, driving and operating machinery should be avoided if you are affected.

3. How to take Rabeprazole Sodium

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
- Only remove a tablet from the blister strip when it is time to take your medicine.
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets.
- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition. When Rabeprazole Sodium is taken once daily, the tablets should be taken in the morning before breakfast.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

The recommended dose is:

Adults and elderly
Duodenal ulcer and benign gastric ulcer*:* 20 mg of Rabeprazole Sodium to be taken once daily in the morning. Most patients with duodenal ulcer are treated for four weeks and most patients with benign stomach ulcer are treated for six weeks. However a few patients may require additional treatment to achieve healing.

Gastro-Oesophageal Reflux Disease (GORD) with ulcer*:* 20 mg of Rabeprazole Sodium to be taken once daily for four to eight weeks.

Long term treatment of GORD: 10 mg or 20 mg of Rabeprazole Sodium once daily depending upon response.

Symptomatic treatment of GORD*:* 10 mg of Rabeprazole Sodium once daily for 4 weeks. Once symptoms have cleared your doctor may tell you to take 10 mg of Rabeprazole Sodium once daily when needed for subsequent symptom control.

Zollinger-Ellison Syndrome*:* 60 mg of Rabeprazole Sodium once a day to start with. The dose may then be adjusted by your doctor depending on how you respond to the treatment. Your doctor will tell you how many tablets to take and when to take them.

Eradication of *H. pylori*: 20 mg of Rabeprazole Sodium to be taken twice each day and normally for 7 days (in combination with two antibiotics - clarithromycin and amoxicillin).

Use in children
Rabeprazole Sodium are not recommended for use in children.

If you take more Rabeprazole Sodium than you should
If you have taken more Rabeprazole Sodium than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Rabeprazole Sodium

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual
- If you forget to take your medicine for more than 5 days, talk to your doctor before taking any more medicine
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose

If you stop taking Rabeprazole Sodium
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.**

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects are usually mild and improve without you having to stop taking this medicine.

If you notice any of the following serious side effects, stop taking Rabeprazole Sodium and contact a doctor immediately you may need urgent medical treatment:

- Allergic reactions – the signs may include: sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse
- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat
- Bruising or bleeding easily.

These side effects are rare (affect fewer than 1 in 1,000 people).

- Sudden onset of severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN))

These side effects are very rare (affect fewer than 1 in 10,000 people).

Other possible side effects

Common side effects (may affect up to 1 in 10 people):

- cough, sore throat (inflammation of the pharynx), runny nose
- effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation
- aches, back pain, non-specific pain
- weakness or loss of strength, flu like symptoms
- difficulty sleeping
- headache, dizziness
- infection
- benign polyps in the stomach

Uncommon side effects (may affect up to 1 in 100 people):

- feeling nervous or drowsy
- sleepiness
- chest infection (bronchitis)
- painful and blocked sinuses (sinusitis)
- indigestion, dry mouth, belching

- rash, skin redness (erythema)
- muscle pains, joint pains, leg cramps
- bladder infection (urinary tract infection)
- chest pain, chills, fever
- muscle, leg or joint pain
- change in how your liver is working (which is measured by blood tests)
- Fracture of the hip, wrist or spine

Rare side effects (may affect up to 1 in 1000 people):
- blood problems such as reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely
- changes in white blood cells (shown in blood tests) which may result in frequent infection
- allergic reactions including facial swelling, low blood pressure and breathing difficulties
- loss of appetite (anorexia)
- depression
- visual disturbance
- upset stomach or stomach pain, sore mouth, taste disturbance
- inflammation of the liver, jaundice (yellowing of the skin or eyes)
- itchy rash, sweating, skin blisters
- kidney inflammation (interstitial nephritis)
- increased weight

Not known (frequency cannot be estimated from the available data):
- low levels of sodium in the blood which can cause tiredness and confusion, muscle twitching, fits and coma
- confusion
- swelling of the feet and ankles
- enlarged breasts in men
- patients who have previously had liver problems may very rarely get encephalopathy (a brain disease)

- rash, possibly with pain in the joints
- inflammation of the gut (leading to diarrhoea)

If you are on Rabeprazole Sodium 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.

Do not be concerned by this list of side effects. You may not get any of them.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Sodium

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

Blister packs: Store below 25°C. Store in the original package in order to protect from moisture.
Tablet containers: Store below 25°C. Keep the container tightly closed in order to protect from moisture.

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

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 Sodium contains

- The active substance is rabeprazole sodium. Each tablet contains either 10 mg (or 20 mg) of rabeprazole sodium.
- The other ingredients are: *core:* povidone, mannitol (E421), light magnesium oxide, low substituted hydroxypropyl cellulose, magnesium stearate; *sealing:* ethyl cellulose, light magnesium oxide; *gastro-resistant coating:* methacrylic acid-ethyl acrylate copolymer, polysorbate 80, sodium laurilsulfate, propylene glycol, talc, iron oxide red (E172), iron oxide yellow (E172), titanium dioxide (E171).

What Rabeprazole Sodium looks like and contents of the pack

Rabeprazole Sodium 10 mg gastro-resistant tablet: Pink, coated, elliptical, biconvex tablet.
Rabeprazole Sodium 20 mg gastro-resistant tablet: Yellow, coated, elliptical, biconvex tablet.

Pack sizes:
Blister packs: 7, 14, 20, 28, 30, 56, 60, 98, 100 and 120 tablets.
Plastic tablet containers with a desiccant: 30, 100 and 250 tablets.
Plastic tablet containers with an integrated desiccant: 30, 100 and 250 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland

Manufacturer
Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria

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

Ireland	Rabeprazole Sodium 10 mg & 20 mg Gastro-resistant Tablets
United Kingdom	Rabeprazole 10 mg/20 mg Gastro-resistant Tablets

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