Package leaflet: Information for the patient

Rabeprazole Krka 10 mg gastro-resistant tablets
Rabeprazole Krka 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

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

Rabeprazole Krka tablets contain rabeprazole. It belongs to a class of medicines called proton pump inhibitors. They act by reducing the amount of acid made by the stomach.

Rabeprazole Krka tablets are used for:
- Active duodenal ulcer or active benign gastric/stomach ulcer (peptic ulcers).
- Symptomatic erosive or ulcerative gastro-oesophageal reflux disease (GORD) commonly referred to as inflammation of the gullet caused by acid and associated with heartburn, or for long-term treatment of GORD (GORD maintenance).
- The symptomatic treatment of moderate to very severe gastrooesophageal reflux disease (symptomatic GORD) also associated with heartburn.
- Zollinger-Ellison syndrome, a rare condition in patients whose stomachs make extremely high amounts of acid.
- In combination with two antibiotics (clarithromycin and amoxycillin) Rabeprazole Krka tablets are used for the eradication of *H pylori* infection in patients with peptic ulcer disease.

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

Do not take Rabeprazole Krka:
- if you are allergic to rabeprazole sodium or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant, you think you might be pregnant or if you are breast feeding (please see Pregnancy and breast-feeding)

Warnings and precautions
Talk to your doctor or pharmacist before taking Rabeprazole Krka.
Tell your doctor or pharmacist:
- if you are allergic to other proton pump inhibitors
- if you have been told you have a stomach tumour
- if you have a history of liver disease

- if you are taking atazanavir (a drug 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 Krka 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 Krka. Remember to also mention any other ill-effects like pain in your joints.

If you are taking this medicine for a long time, your doctor will want to monitor you.

Blood and liver problems have been seen in some patients but often get better when rabeprazole treatment is stopped.

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

Taking a proton pump inhibitor like Rabeprazole Krka, 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).

When taking rabeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Children and adolescents
Rabeprazole Krka should not be used in children.

Other medicines and Rabeprazole Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Tell your doctor or pharmacist:
- if you are taking ketoconazole or itraconazole (drugs used to treat fungal infections). Rabeprazole Krka may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
- if you are taking atazanavir (a drug used to treat HIV). Rabeprazole Krka may lower the amount of this type of medicine in your blood and they should not be used together.
- if you are taking 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 Krka treatment.

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

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 this medicine.
Do not take Rabeprazole Krka tablets if you are pregnant or think you may be pregnant.
Do not take Rabeprazole Krka tablets if you are breast-feeding or planning to breast-feed.

Driving and using machines
You may feel sleepy while taking Rabeprazole Krka. If this happens, do not drive or use any tools or machines.

Rabeprazole Krka contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Rabeprazole Krka

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

YOU MUST SWALLOW THE Rabeprazole Krka TABLET WHOLE.
DO NOT CRUSH OR CHEW IT.

The dosages below are those usually recommended for adults and the elderly. Do not change the dose or length of the treatment yourself.

Use in children
Rabeprazole Krka should not be used in children.

Active duodenal ulcer and active benign gastric ulcer
The usual dose is one Rabeprazole Krka 20 mg tablet once a day.
If you have an *active duodenal ulcer,* your treatment is expected to continue for four weeks; but after that time your doctor may decide to continue your treatment for a further four weeks.
If you have an *active benign gastric ulcer,* your treatment is expected to continue for six weeks; but after that time your doctor may decide to continue your treatment for a further six weeks.

Erosive or ulcerative gastro-oesophageal reflux disease
The usual dose is one Rabeprazole Krka 20 mg once a day. Your treatment is expected to continue for four weeks; but after that time your doctor may decide to continue your treatment for a further four weeks.

GORD maintenance
The usual dose is one Rabeprazole Krka 10 mg or 20 mg once a day. Your doctor will advise you on how long to take your tablets. You need to see your doctor at regular intervals for review of your tablets and symptoms.

Symptomatic GORD
The usual dose is one Rabeprazole Krka 10 mg once a day. Your once daily treatment is expected to continue for up to four weeks. If your symptoms do not resolve within four weeks consult your doctor. Following this initial four week treatment, if your symptoms return, your doctor may then tell you to take one Rabeprazole Krka 10 mg tablet as and when you require it in order to control your symptoms.

Zollinger-Ellison syndrome
The usual recommended dose is three Rabeprazole Krka 20 mg tablets 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. You need to see your doctor at regular intervals for review of your tablets and symptoms.

Eradication of H. pylori
The usual recommended dose is Rabeprazole Krka 20 mg to be taken (in combination with two antibiotics - clarithromycin 500 mg and amoxycillin 1 g) twice each day and normally for 7 days. Relief of symptoms will normally occur before the ulcer has completely healed. Therefore it is important that you do not stop taking the tablets until told to do so by your doctor. For further information on the other components of the *H. pylori* eradication therapy see the individual product information leaflets.

If you take more Rabeprazole Krka than you should
Do not take more tablets each day than you are prescribed. If you accidentally take more tablets than the prescribed dose, please consult your doctor or go to the hospital straight away. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

If you forget to take Rabeprazole Krka
If you forget to take a dose, just take it immediately when you remember, and then continue as usual.
If you forget to take your medicine for more than 5 days, call your doctor before taking any more medicine.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Rabeprazole Krka
Do not change the dosage or stop the medication without discussing it with your doctor first.

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 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.

Stop taking Rabeprazole Krka and see a doctor straight away if you notice any of the following side effects - 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 (may affect up to 1 in 1,000 people).
- Severe skin blistering, or soreness or ulcers in your mouth and throat

These side effects are very rare (may affect up to 1 in 10,000 people).

Other possible side effects:
Common (may affect up to 1 in 10 people**):**
- Infection
- Insomnia (difficult sleeping)
- Headaches, dizziness
- Cough, pharyngitis (sore throat), rhinitis (runny nose)
- Diarrhoea, vomiting, nausea, abdominal pain, constipation (costiveness), flatulence (wind), benign polyps in the stomach
- Pain without any known cause, back pain
- Asthenia (weakness), flu like syndrome

Uncommon (may affect up to 1 in 100 people**):**
- Nervousness or drowsiness
- Bronchitis, sinusitis
- Dyspepsia (indigestion), dry mouth, eructation (belching)
- Skin rash, redness of the skin
- Muscle or joint pain, leg cramps, fracture of the hip, wrist or spine
- Urinary tract infection
- Chest pain
- Chills, fever
- Changes in liver function test values

Rare (may affect up to 1 in 1,000 people**):**
- Anorexia (loss of appetite)
- Depression
- Hypersensitivity (including allergic reactions)
- Vision disturbances
- Gastritis (upset stomach or stomach pain), stomatitis (sore mouth), taste disturbances
- Liver problems such as hepatitis (inflammation of the liver) and jaundice (yellowing of your skin and whites of your eyes), hepatic encephalopathy (brain damage due to liver disease)
- Itching, sweating, skin blisters (these reactions have usually resolved after discontinuation of therapy)
- Sweating
- Kidney problems such as interstitial nephritis (disorders of the connective tissue within the kidney)
- Weight gain
- Changes in white blood cells (shown in blood tests) which may result in frequent infection
- Thrombocytopenia (decrease of blood platelets) - reduction in blood platelets resulting in bleeding or bruising more easily than normal

Frequency not known (frequency cannot be estimated from the available data**):**
- Confusion
- Swelling of the feet or ankles
- Breast swelling in men
- Hyponatremia (low levels of sodium in the blood) – the symptoms are feeling sick and unwell with weak muscles or confused
- 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
Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rabeprazole Krka

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 packaging. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture and light.
Do not store above 30°C.

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 Krka contains

- The active substance is rabeprazole sodium.
  Rabeprazole Krka 10 mg gastro-resistant tablets
  Each gastro-resistant tablet contains 10 mg rabeprazole sodium equivalent to 9.42 mg rabeprazole.
  Rabeprazole Krka 20 mg gastro-resistant tablets
  Each gastro-resistant tablet contains 20 mg rabeprazole sodium equivalent to 18.85 mg rabeprazole.
- The other ingredients are mannitol (E421), light magnesium oxide (E530), hydroxypropylcellulose (E463), low-substituted hydroxypropylcellulose (E463) and magnesium stearate (E470b) in the tablet core, and ethylcellulose (E462), light magnesium oxide (E530), hypromellose phthalate, diacetylated monoglycerides (E472a), talc (E553b), titanium dioxide (E171), red iron oxide (E172) (10 mg only) and yellow iron oxide (E172) (20 mg only) in the coating. See section 2 “Rabeprazole Krka contains sodium”.

What Rabeprazole Krka looks like and contents of the pack

10 mg gastro-resistant tablets are orange-pink, biconvex, round tablets with bevelled edges, tablet diameter approximately 5.7 mm.
20 mg gastro-resistant tablets are slightly brownish yellow, biconvex, round, tablet diameter approximately 7.2 mm.

For both strengths, boxes of 7, 10, 14, 15, 28, 30, 56, 60, 90, 98 and 100 gastro-resistant tablets in blisters are available.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	**Name of the medicine**
Netherlands	Beryx
France, Ireland	Rabeprazole Krka
Finland, Iceland	Rabeprazol Krka

This leaflet was last revised in