

Package leaflet: Information for the patient

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, 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 is and what it is used for
2. What you need to know before you take Rabeprazole
3. How to take Rabeprazole
4. Possible side effects
5. How to store Rabeprazole
6. Contents of the pack and other information

The name of your medicine is Rabeprazole 10 mg or 20 mg Gastro-resistant Tablets (referred to as Rabeprazole throughout this leaflet).

1. What Rabeprazole is and what it is used for

Rabeprazole contains rabeprazole which belongs to a group of medicines called 'Proton Pump Inhibitors' (PPIs). They work by lowering the amount of acid that your stomach produces.

Rabeprazole tablets can be used to treat the following conditions:

- Symptomatic treatment of erosive or ulcerative 'Gastro-Oesophageal Reflux Disease' (GORD) commonly referred to as inflammation of the gullet caused by stomach acid and associated with heartburn, or for long-term treatment of GORD (GORD maintenance). GORD is caused when acid and food from your stomach escapes into your food pipe and can cause inflammation (oesophagus).
- The symptomatic treatment of moderate to very severe gastro-oesophageal reflux disease (symptomatic GORD) also associated with heartburn.
- Ulcers in your stomach or the upper part of your gut (intestine). If these ulcers are infected with bacteria called '*Helicobacter pylori*' (*H. Pylori*), you will also be given antibiotics. Using Rabeprazole tablets and antibiotics together gets rid of the infection and makes the ulcer heal. It also stops the infection and ulcer from coming back.
- Zollinger-Ellison Syndrome where your stomach produces too much acid.

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 or think that you are pregnant
- if you are breast-feeding

If you are not sure, talk to your doctor or pharmacist before using rabeprazole.

Also see Pregnancy and breast-feeding section.

Warnings and precautions

Talk to your doctor or pharmacist before taking Rabeprazole

- If you are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles' (such as lansoprazole, omeprazole, esomeprazole, pantoprazole)
- If you have a tumour in the stomach or food pipe. Your doctor may carry out certain tests to rule out cancer before starting treatment with rabeprazole.
- If you have severe liver problems.
- If you are taking atazanavir - for HIV infection (see section 2, Other medicines and 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).
- 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 are due to have a specific blood test (Chromogranin A).

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

During treatment

- Blood problems (such as reduction in blood cells which may cause more frequent infections and fever or easy bruising and bleeding) and liver problems (such as an increase or decrease in liver enzymes which may be seen in blood tests) have been seen in some patients but often get better when Rabeprazole is stopped.
- 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.
- 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 are taking this medicine for a long time, your doctor will want to monitor you.

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 is not recommended in children because there is no experience of its use in this group.

Other medicines and Rabeprazole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This include medicines obtained without a prescription, including herbal medicines.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole or itraconazole – used to treat infections caused by a fungus. Rabeprazole may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
- Atazanavir– used to treat HIV infection. 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 and inflammatory conditions) – 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 apply to you, talk to your doctor or pharmacist before taking Rabeprazole.

Pregnancy and breast-feeding

- Do not use Rabeprazole if you are pregnant or think you may be pregnant
- Do not use Rabeprazole if you are breast-feeding or planning to breast-feed

Driving and using machines

You may feel sleepy while taking Rabeprazole. If this happens, do not drive or use any tools or 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

- Only remove a tablet from the blister strip or bottle 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

Adults and the Elderly

For ‘Gastro-Oesophageal Reflux Disease’ (GORD)’

Treatment of moderate to severe symptoms (symptomatic GORD)

- The recommended dose is one Rabeprazole 10 mg tablet once a day for up to 4 weeks
- Take the tablet in the morning before eating
- If your condition returns after 4 weeks treatment, your doctor may tell you to take one Rabeprazole 10 mg tablet as and when you require it.

Treatment of more severe symptoms (erosive or ulcerative GORD)

- The recommended dose is one Rabeprazole 20 mg tablet once a day for 4 to 8 weeks
- Take the tablet in the morning before eating.

Long-term treatment of symptoms (GORD maintenance)

- The recommended dose is one Rabeprazole 10 mg or 20 mg tablet once a day for as long as your doctor has told you
- Take the tablet in the morning before eating
- Your doctor will want to see you at regular intervals to check your symptoms and dosage.

For ulcers of the stomach (peptic ulcers)

- The recommended dose is one Rabeprazole 20 mg tablet once a day for 6 weeks
- Take the tablet in the morning before eating
- Your doctor may tell you to take Rabeprazole for another 6 weeks if your condition does not improve.

For ulcers of the intestine (duodenal ulcers)

- The recommended dose is one Rabeprazole 20 mg tablet once a day for 4 weeks
- Take the tablet in the morning before eating
- Your doctor may tell you to take Rabeprazole for another 4 weeks if your condition does not improve.

For ulcers caused by *H. Pylori* infection and to stop them coming back

- The recommended dose is one Rabeprazole 20 mg tablet twice a day for seven days
- Your doctor will also tell you to take two antibiotics called amoxicillin (1 mg) and clarithromycin (500 mg).

For further information on the other medicines used for the *H. Pylori* treatment, see the individual product information leaflets.

Zollinger-Ellison Syndrome where excess acid is produced in the stomach

- The recommended dose is three Rabeprazole 20 mg tablets once a day to start with. The dose may be increased to three Rabeprazole 20 mg tablets twice daily. Single daily doses up to 100mg (five Rabeprazole 20 mg tablets) per day may be given.
- The dose may then be adjusted by your doctor depending on how you respond to the treatment.

If you are on long-term treatment you will need to see your doctor at regular intervals for review of your tablets and symptoms.

Use in children

This medicine should not to be used in children because there is no experience of its use in this group.

Patients with liver problems

You should consult your doctor who will take special care when beginning treatment with Rabeprazole and while you continue to be treated with Rabeprazole.

If you take more Rabeprazole than you should

If you take more Rabeprazole 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

- 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 to make up for a forgotten dose.

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.**

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 or moderate and improve without you having to stop taking this medicine.

Stop taking Rabeprazole and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

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

- Fracture of the hip, wrist or spine

Rare (may affect up to 1 in 1,000 people):

- 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. This may be due to decrease in certain type of white blood cells.
- Liver problems including inflammation of the liver (hepatitis), yellowing of your skin and whites of your eyes (jaundice), patients who have previously had liver problems may get hepatic encephalopathy (brain damage due to liver disease)

Very rare (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).

Not known (frequency cannot be estimated from the available data):

- Rash, possibly with pain in the joints.

Other possible side effects:

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

- Infections
- Difficulty sleeping
- Headache or feeling dizzy
- Cough, sore throat (pharyngitis), runny nose
- Effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation
- Aches or back pain
- Weakness, flu-like symptoms.
- Benign polyps in the stomach

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

- Feeling nervous, drowsy
- Chest infection (bronchitis)
- Painful and blocked sinuses (sinusitis)
- Dry mouth
- Indigestion, belching
- Skin rash or redness
- Muscle, leg pain or cramps, or joint pain
- Bladder infection (urinary tract infection)
- Chest pain
- Chills, fever
- Changes in how your liver is working (shown in blood tests).

Rare (may affect up to 1 in 1,000 people):

- Loss of appetite (Anorexia)
- Depression
- Visual disturbance

- Sore mouth (stomatitis) or taste disturbance
- Upset stomach or stomach pain
- Itchy rash
- Sweating
- Kidney problems
- Weight gain
- Increase in certain type of white blood cells (leucocytosis)
- Reduction in blood platelets resulting in bleeding or bruising more easily than normal.

Very rare (may affect up to 1 in 10,000 people)

- A rash with measles-like round patches (erythema multiforme).

Not known (frequency cannot be estimated from the available data):

- Confusion
- Breast swelling in men
- Fluid retention which may cause swelling of the hands and legs
- Low blood levels of sodium, which can cause tiredness and confusion, muscle twitching, fits and coma
- 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; Email: 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 blister strips, bottle label or carton after EXP. The expiry date refers to the last day of that month.

Your medicine should be used within 60 days after the bottle is first opened. Therefore, you must throw away the bottle 60 days after you first opened it, even if some tablets are left. To help you remember, write down the date that you opened it in the space on the bottle label.

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

Do not use this medicine if you notice a change in colour of the tablet during its use.

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 Rabeprazole 10 mg Gastro-resistant Tablet contains 9.42 mg rabeprazole.

Each Rabeprazole 20 mg Gastro-resistant Tablet contains 18.85 mg rabeprazole.

The other ingredients are:

Core:

Mannitol, magnesium oxide, heavy, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium stearate, ethylcellulose, iron oxide red (E 172) (for 10 mg only), iron oxide yellow (E 172) (for 20 mg only), hypromellose phthalate, acetylated mono and diglycerides, talc, titanium dioxide (E 171).

Film-coating – 10 mg tablets:

HPMC 2910/Hypromellose 6cP, titanium dioxide (E171), acetylated monoglycerides and iron oxide red (E172).

Film-coating – 20 mg tablets:

HPMC 2910/Hypromellose 6cP, titanium dioxide (E171), acetylated monoglycerides and iron oxide yellow (E172).

Printing ink:

Shellac~45% (20% Esterified), iron oxide black (E172), propylene glycol and ammonium hydroxide (28%).

What Rabeprazole looks like and contents of the pack

Rabeprazole 10 mg Gastro-resistant Tablet is a pink, film-coated, round, biconvex tablet imprinted with 'R3' in black ink on one side of the tablet and blank on the other side.

Rabeprazole 20 mg Gastro-resistant Tablet is a yellow, film-coated, round, biconvex tablet imprinted with 'R4' in black ink on one side of the tablet and blank on the other side.

The tablets are packed in blister strips or bottles and come in pack sizes containing:

Blisters: 7, 14, 28, 30, 50, 56, 98, 100 tablets

Bottles: 30, 100 tablets

Perforated unit dose blister strips: 14 x 1, 28 x 1 and 50 x 1 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd.,
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35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13

Manufacturer

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

Czech Republic	Rabeprazole Mylan 20 mg Enterosolventní tableta
France	Rabeprazole Mylan 10 mg, 20 mg Comprimé gastro-résistant
Greece	Rabeprazole Mylan 10 mg, 20 mg Γαστροανθεκτικό δισκίο
Hungary	Rabeprazole Mylan 10 mg, 20 mg Gyomornedv-ellenálló tableta
Ireland	Rabeprazole 10 mg, 20 mg Gastro-resistant tablets
Italy	Rabeprazolo Mylan Generics 10 mg, 20 mg Compresa gastroresistente
Portugal	Vagrilane 10 mg, 20 mg Comprimido gastrorresistente
Spain	Rabeprazol Mylan 10 mg, 20 mg Comprimidos gastrorresistentes EFG
The Netherlands	Rabeprazolnatrium Mylan 10 mg, 20 mg Maagsapresistente tablet
United Kingdom	Rabeprazole sodium 10 mg, 20 mg Gastro-resistant tablets

This leaflet was last revised in 02/2017.