Package leaflet: Information for the patient

Razole 10 mg gastro-resistant tablets
Razole 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

ROWA®

1 What Razole is and what it is used for

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

Razole 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.

Razole 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, Razole 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 tumours 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 Razole

Do not take Razole
- 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 Razole
- 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 Razole)
- if you are taking an immunosuppressant medicine called methotrexate (see section 2, Other medicines and Razole)
- 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 B_{12} and receive rabeprazole long-term treatment. As with all acid reducing agents, rabeprazole may lead to a reduced absorption of vitamin B_{12}.
- if you have ever had a skin reaction after treatment with a medicine similar to Razole 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 Razole. Remember to also mention any other ill-effects like pain in your joints.

<u>During treatment</u>
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 Razole 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 Razole. You should be regularly checked.

Children
The use of Razole in children is not recommended.

Other medicines and Razole
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Razole 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 Razole if you are pregnant, planning to become pregnant or breast-feeding.

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

3 How to take Razole

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

When administering Razole 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: Razole 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 100 mg/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.
- *For pain or discomfort caused by gastric acid that flows back into the oesophagus without active ulcer:* Usually 4 weeks.

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- *To prevent the recurrence of the disease:* Your doctor will tell you how long the tablets should be taken.
- *For eliminating Helicobacter pylori*: Usually 7 days.
- *For Zollinger-Ellison Syndrome:* As long as the condition requires treatment.

If you take more Razole than you should
If you have accidentally taken too many tablets, contact your doctor, pharmacist or hospital.

If you forget to take Razole
If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Razole
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 medicine can cause side effects, although not everybody gets them.

The following are serious side effects. If you experience any of them, contact your doctor immediately:

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):
– Severe allergic reaction – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), decreased blood pressure, and you may feel you are going to faint
– An increase in infections or fever e.g. sore throat or mouth ulcers which may be due to decrease in certain type of white blood cells
– Inflammation of the liver which may include symptoms such as yellowing of the skin or eyes, pale stools or stomach pain, patients who have previously had liver problems may get brain damage due to liver disease (hepatic encephalopathy).

Very rare (may affect up to 1 in 10,000 people):
– Severe skin reactions including reddening of the skin over your whole body, intense skin rash, blistering of the lips, eyes or mouth or genitals, peeling of the skin, inflammation of the mucous membrane and fever.

Other possible side effects:

Common (may affect up to 1 in 10 people):
– Headache
– Diarrhoea
– Nausea (feeling sick)
– Vomiting (being sick)
– Abdominal pain
– Constipation
– Dizziness
– Coughing
– Runny nose
– Inflammation in the throat
– Infection
– Insomnia (difficulty sleeping)
– Flatulence (gas)
– Pain without any known cause, back pain
– Flu-like symptoms
– Asthenia (unusual weakness)
– Benign polyps in the stomach.

Uncommon (may affect up to 1 in 100 people):
– Elevated liver enzymes
– Digestive problems
– Burping
– Nervousness
– Sleepiness
– Leg cramps
– Chest pains
– Cold shivers
– Fever
– Urinary tract infection
– Muscular pain
– Joint pain
– Bronchitis (inflammation of wind pipe)
– Sinusitis (inflammation of the sinuses with symptoms such as severe headache, stuffy nose, cough and congestion)
– Skin reddening
– Rash
– Dry mouth.

Rare (may affect up to 1 in 1,000 people):
– Severe kidney problems (interstitial nephritis). You may pass little or no urine, have cloudy urine or blood in the urine or have severe pain in the lower back.
– Loss of appetite (Anorexia)
– Bruising or bleeding more easily or without explanation. This may be due to decrease in certain type of blood cells called platelets (Thrombocytopenia).
– Increased white blood cell count which may be seen in blood tests
– Sweating
– Weight gain
– Feeling depressed
– Visual disturbances
– Oral inflammation which includes inflammation of the mouth and lips
– Taste disturbance
– Inflammation of the inner lining of stomach (Gastritis)
– Itching
– Subepidermal blisters.

Very rare (may affect up to 1 in 10,000 people):
– A rash with measle-like round patches (erythema multiforme).

Not known (frequency cannot be estimated from the available data):
– Hyponatremia (low levels of sodium, which can cause tiredness and confusion, muscle twitching, fits and coma)
– Confusion
– Breast development in males
– Swelling of the ankles-feet-legs
– If you are on Razole 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.
– Rash, possibly with pain in the joints.

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 Razole

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

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

Do not store above 25°C. Store in the original package.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

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 Razole contains
The active substance is rabeprazole sodium.

Each Razole 10 mg gastro-resistant tablet contains 10 mg rabeprazole sodium.

Each Razole 20 mg gastro-resistant tablet contains 20 mg rabeprazole sodium.

The other ingredients are:

Tablet core: mannitol, heavy magnesium oxide, hydroxypropyl cellulose, magnesium stearate.

Intermediate layer: ethylcellulose, heavy magnesium oxide.

Tablet coating: hypromellose phthalate, dibutyl sebacate, yellow iron oxide (only Razole 20 mg gastro-resistant tablets), red iron oxide (only Razole 10 mg gastro-resistant tablets), titanium dioxide, talc.

What Razole looks like and contents of the pack

Razole 10 mg gastro-resistant tablets: Pink, film-coated, biconvex tablets.

Razole 20 mg gastro-resistant tablets: Yellow, film-coated, biconvex tablets.

The tablets are supplied in blister packs of 1, 5, 7, 14, 15, 25, 28, 30, 50, 56, 75, 98 or 120 tablets.

Not all pack sizes or tablet strengths may be marketed.

Marketing Authorisation Holder
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Bantry,
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Ireland.

Manufacturer
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