

## **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**

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

#### **1. What Razole is and what it is used for**

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

Razole is used to treat the following conditions:

- 'Gastro-oesophageal reflux disease' (GORD), which can include heartburn. GORD is caused when acid and food from your stomach escapes into your food pipe (oesophagus)
- 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 Razole 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.

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Razole:

- if you are allergic to other proton pump inhibitors or ‘substituted benzimidazoles’
- blood and liver problems have been seen in some patients but often get better when Razole is stopped
- 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 have severe liver disease or have ever had liver problems
- if you are taking a medicine called atazanavir for HIV infection
- if you are taking an immunosuppressant medicine called methotrexate (see section 2, Other medicines and Razole)
- 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<sub>12</sub> and receive long-term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B<sub>12</sub>.
- if you have ever had a skin reaction after treatment with a medicine similar to Razole 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 Razole. Remember to also mention any other ill-effects like pain in your joints.
- if you are due to have a specific blood test (Chromogranin A)
- 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.

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

This medicine may affect the way that your body absorbs vitamin B<sub>12</sub>, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B<sub>12</sub>:

- extreme tiredness or lack of energy
- pins and needles
- sore or red tongue, mouth ulcers
- muscle weakness
- disturbed vision
- problems with memory, confusion, depression

### **Children**

Razole should not be used in children.

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

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.

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).

### **Other medicines and Razole**

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. 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. Razole 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. Razole may lower the amount 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 Razole treatment.

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

### **Pregnancy, breast-feeding and fertility**

- Do not use Razole if you are pregnant or think you may be pregnant.
- Do not use Razole 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**

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

### **Razole 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 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**

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

**Adults and elderly**

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

**For 'gastro-oesophageal reflux disease' (GORD)****Treatment of moderate to severe symptoms (symptomatic GORD)**

- The recommended dose is one Razole 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 Razole 10 mg tablet as and when you require it.

**Treatment of more severe symptoms (erosive or ulcerative GORD)**

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

**For ulcers of the intestine (duodenal ulcers)**

- The recommended dose is one Razole 20 mg tablet once a day for 4 weeks
- Take the tablet in the morning before eating
- Your doctor may tell you to take Razole 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 Razole 20 mg tablet twice a day for seven days
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin. 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 Razole 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.

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

**Patients with liver problems.** You should consult your doctor who will take special care when beginning treatment with Razole and while you continue to be treated with Razole.

**If you take more Razole 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 Razole**

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, call 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 Razole**

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.

**Stop taking Razole 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: swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse
- Frequent infections, such as 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.

#### **Other possible side effects:**

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

- Infections
- Difficulty sleeping
- Headache or feeling dizzy
- Cough, runny nose or sore throat (pharyngitis)
- 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 or flu like symptoms
- Benign polyps in the stomach.

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

- Feeling nervous or drowsy
- Chest infection (bronchitis)
- Painful and blocked sinuses (sinusitis)
- Dry mouth
- Indigestion or belching
- Skin rash or redness
- Muscle leg or joint pain
- Fractures of the hip, wrist and spine

- 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
- Hypersensitivity (includes allergic reactions)
- Vision disturbances
- Sore mouth (stomatitis) or taste disturbance
- Upset stomach or stomach pain
- Liver problems including yellowing of your skin and whites of your eyes (jaundice)
- Itchy rash or blistering skin
- Sweating
- Kidney problems
- Weight gain
- Changes in white blood cells (shown in blood tests) which may result in frequent infection
- Reduction in blood platelets resulting in bleeding or bruising more easily than normal
- 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 measles-like round patches (erythema multiforme).

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

- Breast swelling in men
- Fluid retention
- Inflammation of the gut (leading to diarrhoea)
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Low blood levels of magnesium (see section 2 “What you need to know before you take Razole”)
- Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease)
- Rash, possibly with pain in the joints.

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 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](http://www.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, equivalent to 9.42 mg rabeprazole.

Each Razole 20 mg Gastro-resistant tablet contains 20 mg rabeprazole sodium, equivalent to 18.85 mg rabeprazole.

The other ingredients are:

*Tablet core:* mannitol (E421), magnesium oxide, heavy (E 530), hydroxypropyl cellulose (E463), magnesium stearate (E572).

*Intermediate layer:* ethylcellulose (E462), magnesium oxide, heavy (E 530).

*Tablet coating:* hypromellose phthalate, dibutyl sebacate, yellow iron oxide (E172) (only Razole 20 mg gastro-resistant tablets), red iron oxide (E172) (only Razole 10 mg gastro-resistant tablets), titanium dioxide (E171), 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**

Rowa Pharmaceuticals Ltd.  
Bantry  
Co. Cork  
Ireland

### **Manufacturer**

Laboratorios LICONSA, S.A.  
Avda. Miralcampo, N° 7, Polígono Industrial Miralcampo  
19200 Azuqueca de Henares (Guadalajara), SPAIN

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

Denmark:	Ralic 10 mg enterotablett Ralic 20 mg enterotablett
Greece:	Aircodos 10 mg Γαστροανθεκτικό δισκίο Aircodos 20 mg Γαστροανθεκτικό δισκίο
Hungary:	Ralic 10 mg gyomornedv-ellenálló tabletta Ralic 20 mg gyomornedv-ellenálló tabletta
Ireland:	Razole 10 mg Gastro-resistant tablets Razole 20 mg Gastro-resistant tablets
Portugal:	Ralic, 10 mg, Comprimido gastrorresistente

Spain: Ralic, 20 mg, Comprimido gastrorresistente  
Rabeprazol Kern Pharma 10 mg comprimidos gastrorresistente EFG  
Rabeprazol Kern Pharma 20 mg comprimidos gastrorresistente EFG

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