

Package leaflet: Information for the patient

**Rabeprazole Sodium Actavis 10 mg Gastro-resistant Tablets
Rabeprazole Sodium Actavis 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 Actavis is and what it is used for
2. What you need to know before you take Rabeprazole Sodium Actavis
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1. What Rabeprazole Sodium Actavis is and what it is used for

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

Rabeprazole Sodium Actavis 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 Actavis may be used as a long term treatment of GORD (GORD maintenance). Rabeprazole Sodium Actavis 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 Actavis 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 Actavis

Do not take Rabeprazole Sodium Actavis

- 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 breast feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Rabeprazole Sodium Actavis

- if you are allergic to other proton pump inhibitors.
- if you have or have had any liver problems.
- if you are taking a medicine called atazanavir (used to treat HIV).
- if you have ever had a skin reaction after treatment with a medicine similar to Rabeprazole Sodium Actavis 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 Actavis. Remember to also mention any other ill-effects like pain in your joints.

If the above applies to you, consult your doctor before taking Rabeprazole Sodium Actavis.

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 Actavis on a long-term basis (longer than 1 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 Actavis, 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).

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 values have been reported during treatment with Rabeprazole Sodium Actavis. Usually, the values become normal when the treatment is discontinued.

Children

Rabeprazole Sodium Actavis is not recommended for use in children.

Other medicines and Rabeprazole Sodium Actavis

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important in case you are taking any of the following medicines:

- atazanavir (used to treat HIV); it is not recommended to take Rabeprazole Sodium Actavis if you are taking atazanavir.
- ketoconazole or itraconazole (used to treat infections caused by a fungus).

Pregnancy and breast-feeding

Rabeprazole Sodium Actavis must not be used during 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.

Driving and using machines

It is unlikely that Rabeprazole Sodium Actavis would affect your ability to drive or operate machinery. However, occasionally rabeprazole can cause sleepiness. Therefore, driving and operating complex machinery should be avoided if you are affected.

3. How to take Rabeprazole Sodium Actavis

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

Adults and elderly

Duodenal ulcer and benign gastric ulcer: 20 mg of Rabeprazole Sodium Actavis 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 Actavis to be taken once daily for four to eight weeks.

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

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

Zollinger-Ellison Syndrome: 60 mg of Rabeprazole Sodium Actavis 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 Actavis to be taken twice each day and normally for 7 days (in combination with two antibiotics - clarithromycin and amoxicillin).

Use in children

Rabeprazole Sodium Actavis is not recommended for use in children.

Instructions for use

The tablets must be swallowed whole with half a glass of water and may not be chewed or crushed. When Rabeprazole Sodium Actavis is taken once daily, the tablets should be taken in the morning before breakfast.

If you take more Rabeprazole Sodium Actavis than you should

If you have taken more Rabeprazole Sodium Actavis than prescribed by your doctor, seek medical advice.

If you forget to take Rabeprazole Sodium Actavis

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop taking Rabeprazole Sodium Actavis and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction).
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis.

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

- cough, sore throat (inflammation of the pharynx), runny nose
- nausea, vomiting, abdominal pain, diarrhoea, constipation, wind (flatulence)
- back pain, non-specific pain
- weakness or loss of strength, flu like symptoms

- sleeplessness
- headache, dizziness
- infection
- benign polyps in the stomach

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

- nervousness
- sleepiness
- inflammation of the bronchial tubes (bronchitis), inflammation of the sinuses (sinusitis)
- indigestion, dry mouth, belching
- rash, skin redness (erythema)
- muscle pains, joint pains, leg cramps
- urinary tract infection
- chest pain, chills, fever
- increased liver enzymes, which is measured by blood tests
- Fracture of the hip, wrist or spine

Rare (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.
- increased number of white blood cells
- allergic reactions including facial swelling, low blood pressure and breathing difficulties
- loss of appetite
- depression
- visual disturbance
- inflammation of the stomach, inflammation of the mouth, taste disturbance
- inflammation of the liver, jaundice (yellowing of the skin or eyes), brain disturbance associated with liver failure (hepatic encephalopathy)
- itching, sweating, skin blisters
- kidney inflammation (interstitial nephritis)
- increased weight

Very rare (may affect up to 1 in 10000 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))

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

- low levels of sodium in the blood
- confusion
- swelling of the feet and ankles
- enlarged breasts in men
- If you are on Rabeprazole Sodium Actavis 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, 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 Actavis

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 Actavis contains

- The active substance is rabeprazole sodium. Each tablet contains 10 mg (or 20 mg) 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 Actavis looks like and contents of the pack

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

Rabeprazole Sodium Actavis 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

Actavis Group PTC ehf, Reykjavíkurvegi 76-78, 220
Hafnarfjörður, Iceland

Manufacturer

Actavis hf, Reykjavíkurvegur 78, 220 Hafnarfjörður, Iceland

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:

Austria	Rabeprazol Actavis 10 mg /20 mg magensaftresistente Tabletten
Bulgaria	Acilesol
Estonia	Rabeprazole Actavis
Germany	Rabeprazol PUREN 10 mg/20 mg magensaftresistente Tabletten
Greece	Rabeprazole/Actavis
Hungary	Acilesol

Iceland	Rabeprazol Actavis
Ireland	Rabeprazole Sodium Actavis 10 mg & 20 mg Gastro-resistant Tablets
Lithuania	Rabeprazole Actavis 10 mg/20 mg skrandyje neirios tabletės
Netherlands	Rabeprazol natrium Auro 10 mg/20 mg maagsapresistente tabletten
Portugal	Rabeprazol Aurovitas (10 and 20 mg)
Spain	Rabeprazol Aurovitas Spain 10 mg/20 mg comprimidos gastrorresistentes EFG
United Kingdom	Rabeprazole 10 mg/20 mg Gastro-resistant Tablets

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