Rabeprazole 10mg and 20mg Gastro-Resistant Tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. • It should be stored tightly closed in the original container and protected from light and dust.

What is in this leaflet
• What Rabeprazole tablets are and what they are used for
• How to take Rabeprazole tablets
• Possible side effects
• How to store Rabeprazole tablets
• Contents of the pack and other information

What Rabeprazole tablets are and what they are used for
Rabeprazole tablets belong to a group of medicines called Proton Pump Inhibitors (PPIs). Rabeprazole tablets act by reducing the amount of acid made by the stomach. Rabeprazole tablets are used to treat: 
• ulcer of the stomach (duodenal ulcer) and brings stomach ulcer:  
• gastro-oesophageal reflux disease (GORD) with or without ulcer. GORD is commonly referred to as heartburn. The symptoms caused by acid and associated with heartburn are feeling burning from the stomach or lower chest up towards the neck. Rabeprazole tablets may be used as a long term treatment of GORD (Gastro-oesophageal reflux disease). Rabeprazole tablets may also be used for the symptomatic treatment of Zollinger-Ellison Syndrome. Rabeprazole tablets may also be useful in the management of other gastrointestinal reflux symptoms. 

Zollinger-Ellison Syndrome, which is a condition when the stomach makes much larger amounts of acid than normal.

In combination with two antibiotics (clarithromycin and amoxicillin) Rabeprazole tablets are used for the eradication of H. pylori infection in patients with ulcers or peptic ulcer disease. For further information on the antibiotics and the new pill eradication therapy see the patient information leaflet.

What you need to know before you take Rabeprazole tablets
Do not take Rabeprazole tablets if you are allergic to rabeprazole sodium or any of the other ingredients. (See section 6.3).

To any other proton pump inhibitor such as omeprazole or lansoprazole.
• have had or have any other lower problems
• are allergic to some other medicines (see section 4). 

How to take Rabeprazole tablets

Adults and elderly

Duodenal ulcer or assigned gastric ulcer: 20mg of Rabeprazole tablets to be taken once daily with or without food. Patients with duodenal ulcer are treated for four weeks and patients with gastric ulcer are treated for six weeks. However a few patients may require an additional treatment to achieve healing.

Gastro-oesophageal reflux disease (GORD) with ulcer: 20mg of Rabeprazole tablets to be taken once daily for 4 weeks.

Long term treatment of GORD: 10mg or 20mg of Rabeprazole tablets to be taken once daily depending upon response.

Symptomatic treatment of GORD: 10mg of Rabeprazole tablets once daily for 4 weeks.

How to stop taking Rabeprazole tablets
If you take too much Rabeprazole tablets, tell your doctor or pharmacist for advice on the necessary amount oftheactiveingredient. 

Some abnormal blood values have been reported during treatment with Rabeprazole tablets. Usually, the values become normal when the treatment is discontinued.

Children
Rabeprazole tablets are not recommended for use in children.

Other medicines and Rabeprazole tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines that are bought without prescription. Tell your doctor or pharmacist if you are taking, have taken or might take any other medicines. This includes any medicines that are bought without prescription. 

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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 tablets would affect your ability to drive or operate machinery. However, occasionally rabeprazole can cause sleepiness. Therefore, driving and operating complex machines should be avoided if you are affected.

How to take Rabeprazole tablets

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The recommended dose is:

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Pregnancy and breastfeeding
Rabeprazo...
If you take more Rabeprazole tablets than you should

If you have taken more Rabeprazole tablets than prescribed, you should contact your doctor, seek medical advice or go to a hospital straight away.

How to report side effects

If you get any side effects, talk to your pharmacist, GP or other medical officer. This includes any possible side effects not listed in this leaflet. You can report side effects directly via the Yellow Card scheme at the MHRA website or by searching for MEDICINES HELD IN THE GRAPE OR Apple App store.

If you think you have experienced a side effect, please contact us for more information on the safety of this medicine.

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 tablets and contact a doctor immediately:

• sudden sweating, swelling of your lips, face or body, rash, laryngitis or difficulties breathing (severe allergic reaction)
• yellow skin, dark urine and tiredness which could be symptoms of liver problems
• reddening of the skin with blisters or peeling and may be accompanied with a high fever and joint pain. There may also be severe blisters bursting in the lips, eyes, mouth, nose and genitals. This could be erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis.

Common side effects may affect up to 1 in 10 people:

• cough, sore throat (inflammation of the mouth, taste disturbance)
• nausea, vomiting, abdominal pain
• diarrhoea, feeling of stools passing
• back pain, non-specific pain
• weakness, feeling of energy loss, flu like symptoms
• sleeplessness
• headache, dizziness
• flatulence
• bloating in the stomach

Uncommon side effects may affect up to 1 in 100 people:

• numbness
• diarrhoea
• inflammation of the bronchial tubes (bronchitis), inflammation of the sinuses (sinusitis)
• indigestion, dry mouth, swallowing difficulty
• rash, redness (erythema)
• muscle twitching, pain, leg cramps
• urinary tract infection
• chest pain or pressure, flaring, increase in heart rate.
• increased liver enzymes, which is measured by blood tests.
• increased number of white blood cells
• itching, sweating, skin blisters
• kidney dysfunction (interstitial nephritis)
• increased weight.

Very rare side effects (may affect up to 1 in 10 000 people):

• blood problems such as reduced number of white cells or platelets. This can cause weakness, bruising or make infections more frequent
• increased number of white blood cells
• allergic reactions including local swelling, low blood pressure and breathing difficulties
• loss of appetite
• depression
• visual disturbances
• inflammation of the stomach, inflammation of the mouth, taste disturbance
• inflammation of the eye, joint pain
• muscle weakness as long as you take this medicine.
• itching, sweating, skin blisters
• liver dysfunction (interstitial nephritis)
• increased weight.

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

• low levels of sodium in the blood
• cough
• swelling of the feet and ankles
• enlarged lymph nodes

If you are on Rabeprazole tablets for more than 1 year, your doctor may decide to perform regular blood tests to monitor your levels of magnesium, sodium and liver function tests.

By reporting side effects you can help provide important information on the safety of this medicine.

Contents of the pack and other information

What Rabeprazole tablets contain

The active substance in Rabeprazole tablets is rabeprazole sodium. Each tablet contains either 10mg or 20mg of rabeprazole sodium.

• The other ingredients are: crospovidone, mannitol (E421), light magnesium oxide, low density polyethylene, cellulose, hydroxypropyl methylcellulose, povidone, light magnesium oxide; gastro resistant coating: crospovidone, iron oxide red (E172), iron oxide yellow (E172), iron oxide black (E133), hydrogenated starch hydrolysate (E460), povidone, polyvinyl alcohol, polyethylene glycol, polyethylene glycol 3000, povidone, hydroxypropyl methylcellulose, crospovidone, titanium dioxide (E171), magnesium stearate; neutral coating: talc, magnesium oxide, magnesium silicate, magnesium stearate, titanium dioxide (E171), hydroxypropyl cellulose, magnesium oxide, polyethylene glycol 400, polyethylene glycol 6000, talc, hydroxypropyl methylcellulose, magnesium stearate, silicon dioxide (E551). The other ingredients are:

10mg gastro-resistant tablet:

• Yellow, coated, elliptical, biconvex tablet.

20mg gastro-resistant tablet:

• Pink, coated, elliptical, biconvex tablet.

What Rabeprazole tablets look like and contents of the pack

Rabeprazole 10mg gastro-resistant tablet. Pink, coated, elliptical, biconvex tablet. Yellow, coated, elliptical, biconvex tablet.

Pack sizes:

30.

Marketing Authorisation Holder

Accord Healthcare Limited

3 Samokovsko Shosse Str.

North Harrow, Middlesex

HA1 4HF

United Kingdom

Manufacturer

Baltpharma Dzepana AD

3 Samokovsko Shosse Str. No. 28

Dzepana 4000

Bulgaria

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01271 385257.