

Rabezol[®]

Rabepazole Sodium

Read this entire leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms 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 Rabezol[®] is and what it is used for
2. What you need to know before you use Rabezol[®]
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1. What Rabezol[®] is and what it is used for

Rabezol[®] contains the active ingredient rabepazole 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.

Rabezol[®] enteric coated tablets are 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 Rabezol[®] enteric coated 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 use Rabezol[®]

Do not take Rabezol[®] if you:

- are allergic (hypersensitive) to rabepazole sodium, or any of the other ingredients of this medicine (listed in Section 6).
 - are breast feeding.
- Do not use Rabezol[®] if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Rabezol[®].

Warnings and precautions

Talk to your doctor or pharmacist before taking Rabezol[®] if:

- You are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles'.
 - Blood and liver problems have been seen in some patients but often get better when Rabezol[®] is stopped.
 - You have a stomach tumor.
 - You have ever had liver problems.
 - If you are taking atazanavir- for HIV infection.
 - If you have reduced body stores or risk factors for reduced vitamin B12 and receive long term treatment with rabepazole sodium. As with all acid reducing agents, rabepazole sodium may lead to a reduced absorption of vitamin B12.
 - If you have ever had a skin reaction after treatment with a medicine similar to Rabezol[®] 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 Rabezol[®]. Remember to also mention any other ill-effects like pain in your joints.
 - 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 using Rabezol[®].
- If you experience severe (watery or bloody) diarrhea with symptoms such as fever, abdominal pain or tenderness, stop taking Rabezol[®] and see a doctor straight away. Taking a proton pump inhibitor like Rabezol[®], 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).

Women:

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.

Children:

Rabezol[®] should not be used in children.

Other medicines and Rabezol[®]:

Please tell your doctor or pharmacist if you are taking or have recently taken 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. Rabezol[®] 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. Rabezol[®] 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) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Rabezol[®] treatment.

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

Driving and using machines

You may feel sleepy while taking Rabezol[®]. If this happens, do not drive or use any tools or machines.

3. How to take Rabezol[®]

Always take this medicine exactly as your doctor 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 older people

For 'gastro-oesophageal reflux disease' (GORD)

Treatment of moderate to severe symptoms (symptomatic GORD)

- The usual dose is one Rabezol[®] 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 Rabezol[®] 10 mg tablet as and when you require it.

Treatment of more severe symptoms (erosive or ulcerative GORD)

- The usual dose is one Rabezol[®] 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 usual dose is one Rabezol[®] 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 usual dose is one Rabezol[®] 20 mg tablet once a day for 6 weeks;
- Take the tablet in the morning before eating;

-Your doctor may tell you to take Rabezol[®] for another 6 weeks if your condition does not improve.

For ulcers of the intestine (duodenal ulcers)

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

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

- The usual dose is one Rabezol[®] 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 usual dose is three Rabezol[®] 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 Rabezol[®] and while you continue to be treated with Rabezol[®].

If you take more Rabezol[®] than you should

If you take more Rabezol[®] 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 Rabezol[®]

- 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 (two doses at the same time) to make up for a forgotten dose.

If you stop taking Rabezol[®]

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 Rabezol[®] 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: 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.
- Bruising or bleeding easily.

These side effects are rare (affect less than 1 in 1,000 people).

-Severe skin blistering, or soreness or ulcers in your mouth and throat.

Other possible side effects:

Common (affect less than 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, diarrhea, 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 (affect less than 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, Itch or joint pain, Fractures of the hip, wrist and spine, Bladder infection (urinary tract infection), Chest pain, Chills or fever, Changes in how your liver is working (shown in blood tests).

Rare (affect less than 1 in 1,000 people)

Loss of appetite (Anorexia), Depression, Hypersensitivity (includes allergic reactions), Visual disturbance, 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.

Do not be concerned by this list of side effects. You may not get any of them.

5. How to store Rabezol[®]

Store below 25°C.

Keep in original pack in intact conditions.

6. Contents of the pack and other information

Rabezol[®] 10: Enteric coated tablet; Box of 15 or 30.

Rabezol[®] 20: Enteric coated tablet; Box of 10 or 30.

Composition:

Rabezol[®] 10: Each enteric coated tablet contains Rabepazole Sodium 10mg.

Excipients: mannitol, magnesium oxide, crospovidone, hydroxypropyl cellulose, magnesium stearate, ethylcellulose, hydroxypropyl methylcellulose phthalate, diacetylated monoglyceride, talc, titanium dioxide, hydroxypropyl methylcellulose, ferric oxide, propylene glycol, shellac, black iron oxide.

Rabezol[®] 20: Each enteric coated tablet contains Rabepazole Sodium 20mg.

Excipients: mannitol, magnesium oxide, Low substituted hydroxypropyl cellulose, Povidone, Sodium hydroxide, Talc, Magnesium Stearate, Ethyl cellulose, Ferric oxide Yellow, Titanium dioxide, Methacrylic Acid copolymer Dispersion, Triethylcitrate, Shellac glaze-45 % in ethanol, Isopropyl alcohol, Iron oxide black, n-Butyl alcohol, Propylene glycol, Ammonium hydroxide 28 %.

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This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use, and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Ministry of Arab Health Ministers
Union of Arab Pharmacists

Benta S.A.L.
Dbayeh - Lebanon