

Package Leaflet: Information for the User

## Rabezole™ 10 mg and 20 mg Enteric coated tablets Rabeprazole sodium

**Read all of this 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Rabezole™ is and what it is used for
2. Before you take Rabezole™
3. How to take Rabezole™
4. Possible side effects
5. How to store Rabezole™
6. Further information

**1. What Rabezole™ is and what it is used for**  
Rabezole™ tablet contains the active ingredient 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.

- Rabezole™ 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 Rabezole™ 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. Before you take Rabezole™

**Do not take Rabezole™ if:**

- You are allergic (hypersensitive) to rabeprazole sodium, or any of the other ingredients of Rabezole™ (listed in Section 6 below).
- You are pregnant or think that you are pregnant.
- You are breast-feeding.

Do not use Rabezole™ if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Rabezole™ Also see Pregnancy and breast-feeding section.

### Children

Rabezole™ should not be used in children.

**Take special care with Rabezole™**

Check with your doctor or pharmacist before taking Rabezole™ 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 Rabezole™ is stopped.
  - You have a stomach tumour.
  - You have ever had liver problems.
  - If you are taking atazanavir- for HIV infection.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Rabezole™.
- If you experience severe (watery or bloody) diarrhoea with symptoms such as fever, abdominal pain or tenderness, stop taking Rabezole™ and see a doctor straight away.

### Using other medicines

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. Rabezole™ 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. Rabezole™ may lower the amount of this type of medicine in your blood and they should not be used together.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Rabezole™.

### Pregnancy and breast-feeding

- Do not use Rabezole™ if you are pregnant or think you may be pregnant.
  - Do not use Rabezole™ if you are breast-feeding or planning to breast-feed.
- Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

### Driving and using machines

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

### 3. How to take Rabezole™

Always take Rabezole™ exactly as your doctor has told you. You should 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 the Elderly

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

- The usual dose is one Rabezole™ 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 Rabezole™ 10 mg tablet as and when you require it.

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

- The usual dose is one Rabezole™ 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 Rabezole™ 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 Rabezole™ 20 mg tablet once a day for 6 weeks.

- Take the tablet in the morning before eating.
- Your doctor may tell you to take Rabezole™ for another 6 weeks if your condition does not improve.

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

- The usual dose is one Rabezole™ 20 mg tablet once a day for 4 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Rabezole™ 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 Rabezole™ 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 Rabezole™ 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.

**Children:** The product should not be used in children.

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

### If you take more Rabezole™ than you should

If you take more Rabezole™ 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 Rabezole™

- 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 Rabezole™

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 product, ask your doctor or pharmacist.

### 4. Possible side effects

Like all medicines, Rabezole™ 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 Rabezole™ 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.

These side effects are very rare (affect fewer than 1 in 10,000 people).

### 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, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation
- Aches or back pain
- Weakness or flu-like symptoms.

**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
- Muscle, leg or joint pain
- 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.

### Other possible side effects (unknown frequency)

- Breast swelling in men
- Fluid retention
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease).

Do not be concerned by this list of side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### 5. How to store Rabezole™

Keep out of the reach and sight of children.  
Do not store above 30 °C. Protect from light.  
Do not use Rabezole™ after the expiry date which is stated on the carton and blister foil.  
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

### 6. Further information

#### What Rabezole™ contains

Each Rabezole™ 10 mg tablet contains 10 mg of the active substance rabeprazole sodium.  
Each Rabezole™ 20 mg tablet contains 20 mg of the active substance rabeprazole sodium.

The other ingredients are: Ludipress, Crospovidone, Magnesium oxide, Microcrystalline Cellulose (Avicel), Povidone K-30, Hydroxypropylcellulose, Colloidal Silicon Dioxide (Aerosil 200), Magnesium Stearate , Opadry White, Hydroxypropyl cellulose AS (Aquat HF), Sodium Hydroxide, Ammonia 30 %, Acryl-eze, Purified Water.

#### What Rabezole™ looks like and contents of the pack

Rabezole™ 10 mg : Off white to pale yellow coloured biconvex enteric-coated tablets imprinted 'JP 52' on one side with black ink.  
Rabezole™ 20 mg : Off white to pale yellow coloured biconvex enteric-coated tablets imprinted 'JP 53' on both sides with black ink.

Rabezole™ 10 mg: Pack of 2 blisters of 7 enteric coated tablets each.  
Rabezole™ 20 mg: Pack of 2 blisters of 7 enteric coated tablets each.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**  
Jamjoom Pharmaceuticals Co., Ltd., Jeddah, Saudi Arabia.  
Tel: +966-2-6081111, Fax: +966-2-6081222.  
Website: www.jamjoompharma.com

#### To report any side effect(s):

- Saudi Arabia:  
National Pharmacovigilance Center (NPC)  
Fax: +966-1-210-7398  
E-mail: npc.drug@sfd.gov.sa,  
Website: www.sfd.gov.sa/npc
- Other GCC States:  
– Please contact the relevant competent authority.

This leaflet was last approved in 02/2013; Version number 01

#### THIS IS A MEDICAMENT

- Medicament is a product that 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.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



**Rabezole™** is a quality product manufactured by:



P.O.Box 6267 Jeddah - 21442- Saudi Arabia  
12500939-Rev 01S/04-02-13