**Patient Information Leaflet**

RABEZOL**®**

Rabeprazole sodium 20 mg, gastro-resistant tablet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. If you notice side effects not mentioned in this leaflet, it is advised to notify the doctor or healthcare professional. Do not pass this medicine on to others.

1. **What is RABEZOL® and what it is used for**

RABEZOL® contains the active ingredient rabeprazole. It belongs to a group of medicines called proton pump inhibitors (PPIs), which act by reducing the production of acid in the stomach. This makes it possible for ulcers to heal, and thereby reduces pain (ATC code: A02BC04)

RABEZOL® is used:

* to treat active ulcers in your upper intestine,
* to treat active benign ulcers in your stomach or peptic ulcers,
* to treat these ulcers in combination with antibiotics when they are infected with bacteria called 'Helicobacter pylori' to stop the infection and let the ulcer heal,
* to treat gastro-oesophageal reflux disease (GORD), commonly referred to as inflammation of the food pipe, associated with pain, discomfort and heart burn caused by reflux of stomach acid into the gullet, including moderate to very severe versions of the disease,
* for the long-term treatment of GORD, to prevent recurrence of the disease after the symptoms have disappeared (GORD maintenance),
* in patients whose stomach makes very high amounts of acid, a condition called Zollinger-Ellison Syndrome.
1. **What you need to know before you take RABEZOL®**

***Do not take RABEZOL® if you are***

* allergic (hypersensitive) to rabeprazole, or any of the other ingredients of this medicine (listed in section 6),
* pregnant or think you may be pregnant or if you are breast-feeding.

***Warnings and precautions***

* *Talk to your doctor or pharmacist before taking RABEZOL®*
* if you are allergic to other proton pump inhibitors (e.g. omeprazole or pantoprazole)
* if you have liver disease: the dosage may be different,
* if you are taking atazanavir (used for HIV/AIDS): the combination is not recommended.
* RABEZOL® is not recommended for use in children.
* There have been reports of patients developing reduced levels of blood platelets or white blood cells during treatment with rabeprazole, which mostly returned to normal after the end of treatment. If you notice unexplained bruising during your treatment with RABEZOL®, please contact your doctor.
* Taking a proton pump inhibitor like RABEZOL® 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 RABEZOL®***

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 RABEZOL® if you are taking atazanavir,
* ketaconazole or itraconazole (used to treat infections caused by a fungus).

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

RABEZOL®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 Rabezol**®** would affect your ability to drive or operate machinery. However, occasionally rabeprazole can cause sleepiness, in that case it is recommended that driving and operating complex machinery be avoided.

1. **How to take RABEZOL®**

**Always take it exactly as your doctor or pharmacist has told you.**

Rabezol**®** gastro-resistanttablets should preferably be taken in the morning, before eating; they should not be chewed or crushed, but swallowed whole with half a glass of water.

The recommended doses are:

* duodenal ulcer and benign gastric ulcer: 1 Rabezol® tablet of 20 mg a day.
* gastro-oesophageal reflux disease (GORD): 1 Rabezol® tablet of 20 mg a day.
* Zollinger-Ellison syndrome: 3 Rabezol**®** tablets of 20 mg a day, in one dose.
* Eradication of H. pylori: 1 Rabezol**®** tablet of 20 mg, to be taken twice each day and normally for 7 days

(in combination with two antibiotics: clarithromycin and amoxicillin).

**If you take more** Rabezol® tablets than prescribed by your doctor, seek medical advice.

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

1. **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** Rabezol® **and consult 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 side effects** (less than 1 in 10): cough, sore throat, running nose, sleeplessness, headache, dizziness, diarrhoea, vomiting, nausea, abdominal pain, constipation, flatulence, non-specific pain, weakness or loss of strength, back pain, flu like symptoms.

**Uncommon side effects**(less than 1 in 100): nervousness, sleepiness, bronchitis, sinusitis, indigestion, dry mouth, belching, rash, skin redness, muscle pain, leg cramps, joint pains, fracture of hip, wrist or spine, urinary tract infection, chest pain, chills, fever, increased liver enzymes (measured by blood tests).

**Rare side effects** (less 1 in 1.000): blood problems such as reduced number of white cells or platelets (can cause weakness, bruising or make infections more likely), 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 side effects** (less than in 10.000): sudden onset of severe rash or blistering or peeling skin (may be associated with a high fever and joint pains: erythema multiforme or Stevens-Johnson syndrome, toxic epidermal necrolysis).

**Frequency not known:** low blood levels of sodium, confusion, swelling in the limbs, enlarging breasts in men.

If you use Rabezol**®** 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.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet.

1. **How to store** Rabezol®**:** Store below 25°C, in the original package, in order to protect from moisture. Keep out of reach and sight of children. Do not use this medicine if the expiry date printed on the pack (Exp.) has passed.
2. **Other information**

**What RABEZOL® contains:** Active Substance: Each gastro-resistant tablet contains 20 mg Rabeprazole sodium**.** List of excipients: Mannitol (E421), Magnesium oxide, Hydroxypropyl cellulose, Sodium starch glycolate, Magnesium stearate / Excipients of gastro-resistant layers: Hypromellose, Propylene glycol, Talc, Methacrylic acid ethylacetate copolymer, Titanium dioxide (E171), Yellow iron oxide (E172), Macrogol, Triethyl citrate.

**RABEZOL®**: box with 14 round, yellow, gastro-resistant tablets, packed in Al/Al foil blisters and a leaflet.

**RABEZOL®** is a prescription only medicine.

Name of Manufacturer: Bilim Ilaç San.ve Tic. A.Ş. GOSB 41480, Gebze-Kocaeli, Turkey.

Registration/Licence Holder: **Dafra Pharma GmbH**, Mühlenberg 7, 4052 Basel, Switzerland.

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