

RABEPRAZOLE SANDOZ® GASRTO-RESISTANT TABLETS 20MG

Rabeprazole sodium (20mg)

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What Rabeprazole Sandoz is used for

Rabeprazole Sandoz is intended for:

- Short-term (4 to 8 weeks) treatment in the healing of erosive or ulcerative Gastroesophageal Reflux Disease (GERD). For those people who have not healed after 8 weeks of treatment, an additional 8-week course of Rabeprazole Sandoz may be considered.
- For maintaining healing and reduction in relapse rates of heartburn symptoms in people with erosive or ulcerative Gastroesophageal Reflux Disease (GERD maintenance).
- Short-term (up to four weeks) treatment in the healing and symptomatic relief of duodenal ulcers.
- Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome.
- Symptomatic treatment of moderate to very severe GERD.
- *Helicobacter pylori* infection eradication to reduce the risk of duodenal ulcer recurrence in adults when used in combination with amoxicillin

and clarithromycin as a three-medicine regimen.

GERD is a long-term condition where acid from the stomach comes up in to the esophagus (tube connecting your mouth and stomach).

How Rabeprazole Sandoz works

Rabeprazole Sandoz is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach.

Before you use Rabeprazole Sandoz

- When you must not use it

Do not take Rabeprazole:

- if you are allergic to rabeprazole sodium or any of the other ingredients of this medicine (see section on ingredients).
- if you are pregnant or breast feeding.

Pregnancy and breast-feeding

Pregnancy

There are no adequate information from the use of Rabeprazole Sandoz in pregnant women. Do not take Rabeprazole Sandoz if you are pregnant, think you may be pregnant, or if you are planning to have a baby. Consult your doctor if you are unsure or need more advice.

Breast-feeding

There is no adequate information on the excretion of Rabeprazole Sandoz into human breast milk. Do not take Rabeprazole Sandoz if you are breast-feeding, or planning to breast-feed. Consult your doctor if you are unsure or need more advice.

Driving and using machines

Rabeprazole sodium might cause "sleepiness". Do not drive or use tools/machines if you experience dizziness or sleepiness.

- Before you start to use it

Talk to your doctor before taking Rabeprazole Sandoz, if any of the following apply to you:

- If you have low platelet and neutrophils level.
- If you have severe liver problems. Doctor will check your liver enzymes more frequently, especially when you are taking Rabeprazole Sandoz as a long-term treatment. If the liver enzyme levels increase, then treatment should be stopped.
- If you are taking acid reducing agents as long-term treatment. As with all acid reducing agents, rabeprazole may lead to a reduced absorption of vitamin B12.
- If you are taking any medicine containing atazanavir (for the treatment of human immunodeficiency virus (HIV)-infection) at the same time as rabeprazole, ask your doctor for specific advice.
- If you are due to have a specific blood test (Chromogranin A)
- If you have osteoporosis or taking corticosteroids (which can increase the risk of osteoporosis).

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicine obtained without a prescription, and herbal medicines. This is because Rabeprazole Sandoz can affect the way some other medicines

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work. Other medicines can also affect the way Rabeprazole Sandoz works. In particular, tell your doctor or pharmacist if you are taking any of the following medicines before you start Rabeprazole Sandoz:

- Atazanavir (antiretroviral medicine for treating HIV)
- Ketoconazole (an antifungal- to treat fungal infection)
- Methotrexate (chemotherapy medicine to treat cancer)

How to use Rabeprazole Sandoz

- How much to use

The usual adult dose for oral use is 10 mg of sodium rabeprazole once daily. However, the dosage may be increased up to 20 mg orally once daily depending on the severity of symptoms.

Adults/elderly:

Healing of Erosive or Ulcerative Gastro-Oesophageal Reflux Disease (GERD):

The recommended oral dose for this condition is 10mg or 20mg twice daily for four to eight weeks. Dose of 20 mg twice daily should only be administered if you have severe mucous membrane injury.

Gastro-Oesophageal Reflux Disease Long-term Management (GERD Maintenance):

For long-term management, a maintenance dose of Rabeprazole Sandoz 20 mg or 10 mg once daily can be used depending upon your response. Dose of 10 mg twice daily may be taken if the treatment is ineffective.

Zollinger-Ellison syndrome:

The recommended adult starting dose is 60 mg once a day. The dose may be increased to 120 mg/day based on individual needs. Single daily doses up to 100 mg/day may be used. 120 mg dose may require divided doses, 60 mg

twice daily. Treatment should continue for as long as advised by your doctor.

Symptomatic treatment of moderate to very severe Gastroesophageal Reflux Disease (symptomatic GERD):

10mg once daily in people without inflammation of esophagus lining. If symptom control has not been achieved during four weeks, consult your doctor for further advice. Once symptoms have resolved, subsequent symptom control can be achieved using an on-demand regimen taking 10mg once daily when needed.

Eradication of *Helicobacter pylori* (bacteria):

Eradication of the bacteria by a combination therapy should be given for 7 days: Rabeprazole Sandoz 20mg twice daily + Clarithromycin 500mg twice daily + Amoxicillin 1000mg twice daily.

Kidney and liver impairment:

No dosage adjustments is necessary.

Rabeprazole Sandoz can be administered at a dose of 20 mg once daily in the case of severe, recurrent and intractable conditions.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

For indications requiring once daily treatment, Rabeprazole Sandoz should be taken in the morning before eating. Use as

directed by your doctor or pharmacist.

- How long to use it

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

- If you forget to use it

It is important to take Rabeprazole Sandoz as your doctor has advised. If you miss a dose, just resume your usual schedule the following day. Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you use too much (overdose)

You should never take more tablets than your doctor recommends. If you do take too many tablets, you should contact your doctor or go the nearest hospital immediately.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Rabeprazole Sandoz to anyone else, even if they have the same symptoms or condition as you.

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- *Things to be careful of*

Be careful when driving or using machinery until you know how this medicine affects you.

Side effects

Like all medicines, Rabeprazole Sandoz can cause side effects, although not everybody gets them. Talk to your doctor or pharmacist immediately if you develop any of the following side effects or if you notice any side effects that is not stated in this leaflet.

When you are taking this medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- Rash (especially in areas exposed to the sun), possible with pain in the joints (subacute cutaneous lupus erythematosus, SCLE)
- Fever, extreme tiredness, pus/blood in urine
- Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate
- Fracture in the hip, wrist or spine
- Osteoporosis
- Watery stool, stomach pain and fever that do not go away
- Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems

(depression, memory loss or behavioral changes).

- Vitamin B12 deficiency (Proton pump inhibitors may cause vitamin B12 deficiency)
- Interstitial nephritis (kidney problem)

The following side effects can occur during treatment with Rabeprazole Sandoz:

Common

- Severe diarrhea which may be caused by an infection (*Clostridium difficile*) in your intestines
- Insomnia or unable to sleep
- Headache, dizziness
- Cough, inflammation of the throat, rhinitis
- Nausea and vomiting
- Abdominal pain
- Constipation
- Flatulence
- Fundic gland polyps (stomach polyps) or gastric (benign polyps in the stomach)
- Pain or back pain
- Weakness, flu-like symptoms

Uncommon

- Nervousness
- Sleepiness
- Inflammation of the airway, inflammation of the sinus cavity
- Gastric reflux, dry mouth, burping
- Rash, redness
- Muscle or joint ache, leg cramps
- Fracture of the hip, wrist or spine
- Chest pain, chills, fever
- Increased liver enzymes
- Fracture
- Osteoporosis (if you are taking corticosteroids)

Rare

- Abnormally low white cell count, platelet count
- Increased white cell count
- Hypersensitivity
- Eating disorder
- Depression
- Visual disturbances
- Inflammation of the stomach, inflammation of the mouth, taste disturbances
- Inflammation of the liver, liver failure, yellowing of the skin and/or eyes (jaundice)
- Itch, sweating, blisters
- Kidney problems
- Increase in weight

Not known

- Low level of magnesium (can lead to a reduction in potassium or calcium levels in the blood) (Hypomagnesaemia)
- SCLE (rash with pain in the joints)
- Inflammation in the large bowel, that causes persistent watery diarrhea

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring or visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Rabeprazole Sandoz

- *Storage*

Do not store above 30°C. Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the pack after "EXP". The expiry date refers to the last day of the month.

- *Disposal*

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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.

Serial Number

NPRA (R2) 19/191

Product Description

- What it looks like

Yellow, round, biconvex, coated tablets.

- Ingredients

- Active ingredient:

Each gastro-resistant tablet contains 20 mg of rabeprazole sodium.

- Inactive ingredients

Excipients:

Calcium hydroxide

Mannitol

Low-substituted hydroxypropyl cellulose

Sodium stearyl fumarate

Hypromellose

Talc

Hypromellose phthalate

Dibutyl sebacate

Yellow ferric oxide (E172)

Titanium dioxide (E171)

MAL Number

MAL20046112ARZ

Manufacturer

Novartis Pharmaceutical

Manufacturing LLC,

Verovskova ulica 57, 1000

Ljubljana, Slovenia.

Product Registration Holder

Sandoz Products Malaysia Sdn. Bhd.

Unit 1202, Level 12, Uptown 1,

No. 1, Jalan SS 21/58,

Damansara Uptown,

47400 Petaling Jaya, Selangor,

Malaysia

Date of Revision

Jan 2024