

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rRABEPRAZOLE

Rabeprazole Sodium Enteric-Coated Tablets

Read this carefully before you start taking **RABEPRAZOLE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **RABEPRAZOLE**.

What is RABEPRAZOLE used for?

RABEPRAZOLE is used in adults to treat conditions where reducing stomach acid production is needed, such as:

- relieve symptoms and heal duodenal ulcers.
- relieve symptoms and heal stomach ulcers.
- heal gastroesophageal reflux disease (GERD) and relieve its symptoms such as:
 - the burning feeling that rises from the chest to the throat (heartburn).
 - the flow of bitter/sour juice into the mouth (regurgitation).
- treat symptoms of non-erosive reflux disease (NERD) such as heartburn and regurgitation
- maintain longer term healing of gastroesophageal reflux disease (GERD).
- treat rare conditions where excess acid is produced in the stomach (e.g., Zollinger-Ellison syndrome).
- treat ulcers caused by infection with the bacterium, *Helicobacter pylori* (*H. pylori*), and prevent these ulcers from coming back by:
 - taking RABEPRAZOLE with antibiotics such as amoxicillin and clarithromycin, as directed by your doctor.
 - following the information on the antibiotics provided to you by the pharmacist.

How does RABEPRAZOLE work?

RABEPRAZOLE is a medicine called a proton pump inhibitor (PPI). RABEPRAZOLE works by reducing the amount of acid made in your stomach.

What are the ingredients in RABEPRAZOLE?

Medicinal ingredients: rabeprazole sodium

Non-medicinal ingredients: calcium hydroxide, dibutyl sebacate, hypromellose, hypromellose phthalate, low-substituted hydroxypropyl cellulose, mannitol, sodium stearyl fumarate, talc, titanium dioxide.

The 10 mg tablet also contains ferric oxide red and ferric oxide yellow as colouring agents.

The 20 mg tablet contains ferric oxide yellow as a colouring agent.

RABEPRAZOLE comes in the following dosage forms:

Tablets of 10 mg and 20 mg

Do not use RABEPRAZOLE if:

- you are allergic to:
 - rabeprazole or other medications in this class
 - the “non-medicinal” ingredients in RABEPRAZOLE tablets. (see **What are the ingredients in RABEPRAZOLE?**)
- you are taking rilpivirine
- you are unable to take amoxicillin or clarithromycin if you are using RABEPRAZOLE to treat ulcers caused by an infection (*H. pylori*)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RABEPRAZOLE. Talk about any health conditions or problems you may have, including if you:

- have any liver problems
- experience symptoms including palpitations (rapid heartbeat), dizziness, seizures, twitching, spasms, muscle weakness, cramps and convulsions. These may be signs of low magnesium levels in your blood
- are taking methotrexate
- are pregnant or planning to become pregnant
- are breast-feeding or planning to breast-feed
- are due to have a specific blood test (Chromogranin A)

Other warnings you should know about:

Long-term use of RABEPRAZOLE may prevent normal absorption of vitamin B₁₂ from the diet and could lead to vitamin B₁₂ deficiency. Talk to your doctor

Using RABEPRAZOLE for a long period of time (a year or longer) may increase the risk of fractures of the hip, wrist or spine. Talk to your doctor about your risk.

Using medicines like RABEPRAZOLE for a long period of time may cause a growth in your stomach (polyp). This can lead to intestinal blockage or bleeding. Talk to your doctor if you experience nausea or stomach pain while you are taking RABEPRAZOLE.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with RABEPRAZOLE:

- ketoconazole
- digoxin
- warfarin
- antiretroviral drugs such as atazanavir, nelfinavir, saquinavir
- methotrexate

How to take RABEPRAZOLE:

- Take RABEPRAZOLE exactly as prescribed by your doctor, usually for a specific number of weeks.
- Use the lowest dose and shortest time as determined by your doctor.
- Do not stop taking RABEPRAZOLE even when you start to feel better. If you stop taking RABEPRAZOLE too soon, your symptoms may return.
- Take RABEPRAZOLE with or without meals.
- Swallow tablets whole with a liquid. Do not chew or crush the tablets.
- Talk to your doctor if you have any concerns.

Usual dose:

Condition	Adult Dose	How often	How long
reflux symptoms with esophagitis	20 mg	once daily	four weeks
reflux symptoms without esophagitis, such as heartburn and regurgitation	10 mg to a maximum of 20 mg	once daily	four weeks
duodenal ulcer	20 mg	once daily	Up to four weeks
stomach ulcer	20 mg	once daily	Up to six weeks
ulcer caused by <i>H. pylori</i> infection ¹	20 mg	twice daily in combination with antibiotic drugs (500 mg clarithromycin and 1000 mg amoxicillin) preferably with the morning and evening meals	one week

1. If you are given RABEPRAZOLE in combination with antibiotic drugs, it is important that you take all medications at the correct time of day and for the entire treatment period to ensure they will work properly. Studies have shown that patients who take their medications as prescribed have better ulcer healing rates and greater success in getting rid of their *H. pylori* infection.

Overdose:

If you think you, or a person you are caring for, have taken too much RABEPRAZOLE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you forget to take one dose of RABEPRAZOLE medication, take a tablet as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed tablet at

all. **Never double-up on a dose to make up for the one you have missed; just go back to your regular schedule.**

What are possible side effects from using RABEPRAZOLE?

Like all medicines, RABEPRAZOLE can cause side effects.

Headache and diarrhea are the most common side effects experienced with RABEPRAZOLE. Less common side effects are rash, itchiness and dizziness. If any of these become troublesome, consult your doctor.

If you experience symptoms of low magnesium levels in your body, your doctor may stop RABEPRAZOLE. Tell your doctor right away if you have any of these symptoms:

- seizures.
- dizziness.
- abnormal or fast heart beat.
- jitteriness.
- jerking movements or shaking (tremors).
- muscle weakness.
- spasms of the hands and feet.
- cramps or muscle aches.
- spasm of the voice box.
- fracture (broken bone).
- Blood in stool.

Stopping your PPI therapy after taking it for a long time, may cause your symptoms to get worse and your stomach may increase acid production. Carefully follow your doctor’s instructions when discontinuing your PPI therapy.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Subacute cutaneous lupus erythematosus (SCLE). New or worsening joint pain and rash that gets worse in the sun		✓	
Severe diarrhea accompanied with blood and/or mucous			✓
<i>Clostridium difficile</i> colitis (Bowel inflammation): Symptoms include severe (watery or bloody) diarrhea, fever, abdominal pain or tenderness			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<i>Clostridium difficile</i> colitis (Bowel inflammation): If you are currently taking or have recently taken antibiotics and you develop diarrhea, contact your doctor, even if the diarrhea is relatively mild.		✓	
<p>Microscopic colitis (inflammation of the gut):</p> <ul style="list-style-type: none"> • Chronic watery diarrhea • Abdominal pain, cramps or bloating • Weight loss • Nausea • Uncontrollable bowel movement • Signs of Dehydration such as Extreme thirst, Less frequent urination, Dark-coloured urine, Fatigue, Dizziness, Confusion <p>The symptoms of microscopic colitis can come and go frequently. If you have watery diarrhea that lasts more than a few days, contact your doctor.</p>	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store in original container between 15°C and 25°C, protected from moisture and heat.

Keep out of the sight and reach of children.

If you want more information about RABEPRAZOLE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.sivem.ca, or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC

Last Revised: August 17, 2023