

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE  
PATIENT MEDICATION INFORMATION**

**Pr RABEPRAZOLE EC  
Rabeprazole Sodium Enteric-Coated Tablets  
10 mg and 20 mg**

Read this carefully before you start taking RABEPRAZOLE EC 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 EC.

**What is RABEPRAZOLE EC used for?**

RABEPRAZOLE EC is used in adults to:

- 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 EC 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 EC work?**

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

**What are the ingredients in RABEPRAZOLE EC?**

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 EC comes in the following dosage forms:**

Tablets of 10 mg and 20 mg

**Do not use RABEPRAZOLE EC if you are allergic to:**

- rabeprazole or other medications in this class
- the “nonmedicinal” ingredients in RABEPRAZOLE EC tablets. (See What are the ingredients in RABEPRAZOLE EC)
- the antibiotics amoxicillin or clarithromycin if these are used with RABEPRAZOLE EC to treat ulcers caused by *H. pylori*

**Do not use RABEPRAZOLE EC if you are:**

- taking rilpivirine

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

- all health problems you have now or have had in the past
- any liver problems
- if you 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
- if you are taking methotrexate
- if you are pregnant or planning to become pregnant
- if you are breast-feeding or planning to breast-feed
- if you are due to have a specific blood test (Chromogranin A)

**Other warnings you should know about:**

Long-term use of RABEPRAZOLE EC may prevent normal absorption of vitamin B<sub>12</sub> from the diet and could lead to vitamin B<sub>12</sub> deficiency. Talk to your doctor

Using RABEPRAZOLE EC 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 EC 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 EC.

**Tell your healthcare professional about all the medicines you take, including any drugs (prescription and non-prescription), vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with RABEPRAZOLE EC:**

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

**How to take RABEPRAZOLE EC:**

- Take RABEPRAZOLE EC 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 EC even when you start to feel better. If you stop taking RABEPRAZOLE EC too soon, your symptoms may return.
- Take RABEPRAZOLE EC 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†	20 mg	twice daily in combination with antibiotic drugs (clarithromycin and amoxicillin) preferably with the morning and evening meals	one week

†If you are given RABEPRAZOLE EC 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 have taken too much RABEPRAZOLE EC, contact your 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 EC 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 EC?**

Like all medicines, RABEPRAZOLE EC can cause side effects.

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

Treatment in combination with antibiotics: If you experience symptoms such as severe diarrhea (bloody or watery) with or without fever, abdominal pain, or tenderness, you may have *Clostridium difficile* colitis (bowel inflammation). If this occurs, stop taking RABEPRAZOLE EC and contact your healthcare professional immediately.

If you experience symptoms of low magnesium levels in your body, your doctor may stop RABEPRAZOLE EC.

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.
- a fracture (broken bone).
- New or worsening joint pain.
- Rash on your cheeks or arms that gets worse in the sun.
- 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.

### **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 EC:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website <http://www.sanis.com>, or by contacting Sanis Health Inc. at:

1-866-236-4076  
or [quality@sanis.com](mailto:quality@sanis.com)

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Last revised: November 5, 2019