

PART III: CONSUMER INFORMATION**PRO-RABEPRAZOLE**
Rabeprazole Sodium Tablets

This leaflet is Part III of a three-part "Product Monograph" published when PRO-RABEPRAZOLE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-RABEPRAZOLE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

Read this leaflet carefully. It contains general information about PRO-RABEPRAZOLE tablets that you should know in addition to the specific advice from your doctor or pharmacist. It is important for you to carefully follow your doctor's instructions regarding how and when to take PRO-RABEPRAZOLE tablets.

What the medication is used for:

PRO-RABEPRAZOLE is the brand name for a drug called rabeprazole sodium.

The most common uses of PRO-RABEPRAZOLE tablets are:

- symptomatic relief and healing of duodenal ulcers;
- symptomatic relief and healing of stomach ulcers;
- healing of gastroesophageal reflux disease (GERD) and relief of its symptoms such as burning sensation rising from the chest towards the neck (heartburn) and the flow of bitter/sour juice into the mouth (regurgitation);
- treatment of symptoms (i.e. heartburn and regurgitation) of non-erosive reflux disease (NERD);
- maintenance treatment of gastroesophageal reflux disease (GERD).

PRO-RABEPRAZOLE tablets may also be used in rare conditions like "Zollinger-Ellison syndrome", where the stomach produces large amounts of acid.

When used with certain antibiotics, PRO-RABEPRAZOLE is also used for the treatment of ulcers caused by infection with a bacterium called *Helicobacter pylori* (*H. pylori*), and to help reduce the risk of these ulcers from coming back. If the doctor is prescribing therapy with a combination of pms-RABEPRAZOLE and antibiotics (amoxicillin and clarithromycin) the pharmacist should provide you with information on the antibiotics.

What it does:

PRO-RABEPRAZOLE is a medicine called a proton pump inhibitor (PPI).

PRO-RABEPRAZOLE works by reducing the amount of acid made in your stomach.

When it should not be used:

If you are allergic to rabeprazole, other medications in this class, to the "nonmedicinal" substances in PRO-RABEPRAZOLE tablets. (See **What the nonmedicinal ingredients are**), or to

the antibiotics amoxicillin or clarithromycin if these are used with PRO-RABEPRAZOLE to treat ulcers caused by *H. pylori*.

What the medicinal ingredient is:

Each PRO-RABEPRAZOLE tablet contains rabeprazole sodium as the medicinal ingredient.

What the nonmedicinal ingredients are:

Both 10 mg tablets and 20 mg tablets contain the following non-medicinal ingredients: Hydroxypropyl cellulose, Hydroxypropyl methylcellulose, Mannitol, Magnesium oxide, Magnesium stearate, Methacrylic acid copolymer, Polyethylene glycol, Shellac glaze, Sodium lauryl sulfate, Talc, Titanium dioxide, Triethyl citrate and Zein.

The 10 mg tablets also contain Antifoam, Hypromellose, Industrial methylated spirit, Iron oxide black, Iron oxide red and Lecithin (soya).

The 20 mg tablets also contain Ammonium Hydroxide, FD&C red No.40 aluminum lake, Propylene Glycol and Yellow iron oxide.

What dosage forms it comes in:

Enteric-coated tablets: 10 mg and 20 mg, rabeprazole sodium.

WARNINGS AND PRECAUTIONS

BEFORE you use PRO-RABEPRAZOLE, tell your doctor:

- about all health problems you have now or have had in the past, including liver problems;
- have been told that you have low magnesium levels in your blood.
- about other medicines you take, including ones you can buy without a prescription (See **Interactions with this medication**);
- if you are pregnant, plan to become pregnant, or are breast-feeding.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PRO-RABEPRAZOLE include: ketoconazole, digoxin, warfarin, atazanavir.

PROPER USE OF THIS MEDICATION

Your doctor has recommended you take PRO-RABEPRAZOLE tablets for a specific number of weeks. Keep taking your PRO-RABEPRAZOLE tablets, as recommended by your doctor, until you have finished all your tablets. Do not stop even when you start to feel better. If you stop taking PRO-RABEPRAZOLE tablets too soon, your symptoms may return.

PRO-RABEPRAZOLE tablets may be taken with or without meals and should be swallowed whole with a beverage, not chewed or crushed.

If you have reflux symptoms with esophagitis:

The recommended adult dose is 20 mg once daily. In most patients the healing occurs in four weeks. If not healed, your doctor may recommend an additional four weeks of treatment.

If you have reflux symptoms without esophagitis, such as heartburn and regurgitation:

The recommended adult oral dose is 10 mg once daily to a maximum of 20 mg once daily in patients without esophagitis. If symptom control is not achieved after four weeks, your doctor may recommend further investigation.

If you have a duodenal ulcer:

The recommended adult dose is 20 mg once daily for up to four weeks. Your doctor may decide to continue treatment to ensure healing depending on your condition.

If you have a stomach ulcer:

The recommended adult dose is 20 mg once daily for up to six weeks. Your doctor may decide to continue treatment to ensure healing depending on your condition.

If you have an ulcer caused by *H. pylori* infection:

The recommended adult dose is 20 mg twice daily used in combination with antibiotic drugs (clarithromycin and amoxicillin) twice daily, preferably with the morning and evening meals, for one week to treat ulcers associated with *Helicobacter pylori* and to help reduce the risk of these ulcers from coming back.

If you are given PRO-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:

In case of drug overdose, contact a health care practitioner (doctor), 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 PRO-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.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, PRO-RABEPRAZOLE tablets may cause side effects in some people. When side effects have been reported, they have been generally mild and did not last a long time. Headache and diarrhea are the most common side effects; less often rash, itchiness and dizziness can occur. If any of these become troublesome, consult your doctor.

If you experience symptoms such as severe (watery or bloody) diarrhea, fever, abdominal pain or tenderness,

you may have *Clostridium difficile* colitis (bowel inflammation).

If this happens, stop taking the drug and call your Health care professional immediately.

If you experience symptoms of low magnesium levels in your body, your doctor may stop PRO-RABEPRAZOLE. This problem can be serious. Low magnesium can happen in some people who take a proton pump inhibitor (PPI) medicine for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium.

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

Your doctor may check the level of magnesium in your body before you start taking PRO-RABEPRAZOLE for a long period of time.

Stopping your PPI therapy after taking it for a long time, may cause an increase in secretion of gastric acid and associated acid-related symptoms. This effect can occur within days to weeks following PPI discontinuation and last for up to several months. Carefully follow your doctor's instructions when discontinuing your PPI therapy.

If you experience any unusual or unexpected symptoms while using PRO-RABEPRAZOLE tablets, consult your doctor.

This is not a complete list of side effects. For any unexpected effects while taking PRO-RABEPRAZOLE, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your tablets stored at room temperature (15°C to 30°C) and protected from moisture. They should be kept in a safe place, where children cannot reach them.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at:
www.healthcanada.gc.ca/medeffect .

NOTE: Should you require information related to the management of side effects, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION**Important Note:**

This information is intended to alert you to which situations you should call your doctor about. Other situations which cannot be predicted may arise while you are taking medicines. Nothing should stop you from calling your doctor with any questions or concerns you have about using PRO-RABEPRAZOLE tablets.

This document plus the full product monograph prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, <http://www.prodoc.qc.ca> or info@prodoc.qc.ca.

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