

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

Pr ESOMEPRAZOLE

Esomeprazole Magnesium Delayed Release Tablets

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

ABOUT THIS MEDICATION

What the medication is used for:

In adults, ESOMEPRAZOLE is used for the treatment of acid related disorders such as:

- reflux esophagitis (tissue damage caused by stomach content flowing back up the food pipe and symptoms of gastroesophageal reflux disease (GERD) in patients with reflux esophagitis
- the symptoms of nonerosive reflux disease (NERD), which are not related to tissue damage within the food pipe, such as: a burning feeling rising from the chest towards the neck (heartburn) and the flow of bitter/sour juice into the mouth (regurgitation)

ESOMEPRAZOLE is also used to heal and/or reduce the risk of ulcers that can be caused by medication you may be taking for pain or joint problems such as NSAIDs (Non-Steroidal Anti-Inflammatory Drugs) or acetylsalicylic acid (i.e. Aspirin®).

In children (12- 17 years of age), ESOMEPRAZOLE is used for the treatment of acid-related disorders such as:

- reflux esophagitis (tissue damage caused by stomach content flowing back up the food pipe) and symptoms of gastroesophageal reflux disease (GERD) in patients with reflux esophagitis
- the symptoms of nonerosive reflux disease (NERD), which are not related to tissue damage within the food pipe, such as: a burning feeling rising from the chest towards the neck (heartburn) and the flow of bitter/sour juice into the mouth (regurgitation).

What it does:

ESOMEPRAZOLE works by causing less acid to be made in your stomach.

When it should not be used:

If you are allergic to the active ingredient esomeprazole or any of the other ingredients of ESOMEPRAZOLE (see what the important non-medicinal ingredients are). If you think you may be allergic, ask your doctor for advice.

What the medicinal ingredient is:

Each ESOMEPRAZOLE tablet contains Esomeprazole magnesium as the active ingredient.

What the important nonmedicinal ingredients are:

ESOMEPRAZOLE contains the following non-medicinal ingredients (listed in alphabetical order): colloidal silicon dioxide, copovidone, magnesium stearate, methacrylic acid copolymer type C, red-ferric oxide, TALC, titanium dioxide, triethyl citrate and yellow ferric oxide.

Check with your doctor or pharmacist if you think you may be allergic to any of the above ingredients.

What dosage forms it comes in:

ESOMEPRAZOLE is available as 20 mg and 40 mg tablets.

WARNINGS AND PRECAUTIONS

BEFORE or DURING your use of ESOMEPRAZOLE talk to your doctor or pharmacist about:

- symptoms that may be a sign of a more serious problem in your stomach or intestine such as: trouble swallowing, unplanned weight loss, vomiting blood or food, or black (blood-stained) stools.
- If you are pregnant or trying to become pregnant
- If you are allergic to esomeprazole or any other ingredients or components of the container
- If you have health problems now or have had any in the past.
- other medications you take, including ones you can buy without a prescription

INTERACTIONS WITH THIS MEDICATION

Blood levels of some drugs may be influenced if ESOMEPRAZOLE is taken at the same time as drugs used to prevent fungal infections (itraconazole, ketoconazole, **voriconazole**), anxiety (diazepam), epilepsy (phenytoin) and drugs to speed up stomach emptying (cisapride*). However, none of these interactions have been shown to change the effectiveness of ESOMEPRAZOLE or the other drug.

Drugs used for blood clotting (warfarin or coumarin derivatives) have been reported to interact with ESOMEPRAZOLE. Speak to your doctor or pharmacist if you are taking any of these drugs.

ESOMEPRAZOLE may decrease the effectiveness of a drug used for HIV treatment (atazanavir and nelfinavir).

During episodic dosing of ESOMEPRAZOLE when needed, your response to potential drug interactions may change as compared to daily dosing during the entire, initial treatment period.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines.

*no longer marketed in Canada.

PROPER USE OF THIS MEDICATION

Administration:

ESOMEPRAZOLE may be taken with food or on an empty stomach. To make sure the tablets are safely and correctly administered, do not disperse, divide, crush or chew the tablets.

Usual dose:

Adults

Take all doses of ESOMEPRAZOLE as directed by your doctor. Do so even when you feel well. In some cases, daily doses are needed to control your pain and symptoms and to help damaged areas heal. The suggested dose for treating acute disease is 20 to 40 mg once a day for 2 to 8 weeks. Your doctor may suggest that you continue taking ESOMEPRAZOLE 20 mg each day. This is to keep your symptoms from coming back.

Follow the directions given to you by your doctor. They may differ from the information contained in this leaflet.

It is important to take ESOMEPRAZOLE until your doctor tells you to stop. This is true even if you start to feel better in a few days. ESOMEPRAZOLE needs to be taken for the full treatment duration to help correct acid problems.

Maintenance Treatment of NERD (on-demand) dose

After initial treatment of NERD, your doctor may suggest that you take ESOMEPRAZOLE 20 mg once daily, as needed, if symptoms of heartburn and regurgitation return periodically. Contact your doctor if your symptoms get worse, persist or if new symptoms arise.

Children (12 – 17 years of age)

ESOMEPRAZOLE IS NOT RECOMMENDED FOR USE IN CHILDREN UNDER 12 YEARS OF AGE

Take all doses of ESOMEPRAZOLE as directed by your doctor. Do so even when you/your child feels well. ESOMEPRAZOLE needs to be taken for the full treatment duration to help correct acid problems.

Follow the directions given to you by your doctor. They may differ from the information contained in this leaflet.

The suggested dose for treating acute disease is 20 or 40 mg once a day for 2 to 8 weeks.

Overdose:

In the event of overdosage, contact your doctor, hospital emergency department or regional Poison Control Centre.

Missed Dose:

If you miss a dose of ESOMEPRAZOLE, and remember within 12 hours, take the tablet as soon as possible. Then go back to your regular schedule. If more than 12 hours have passed, do not take the missed tablet. Do not double the dose. Just take your next dose on time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any drug, ESOMEPRAZOLE may cause side effects in some people. Side effects that do occur are usually mild. They usually go away a short time after starting ESOMEPRAZOLE. These side-effects may not be caused by ESOMEPRAZOLE in your case, but only a doctor can assess this. If these become bothersome (or exceed 1-2 days), discuss with your doctor.

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Common: nausea, stomach upset, diarrhea, headache.

Uncommon: dry mouth, dizziness, insomnia, feeling of burning/prickliness/numbing, swelling of extremities, feeling sleepy, vertigo.

Rare: taste disorders, nervousness, hair loss, increased sweating.

If you experience any bothersome or unusual effects while using ESOMEPRAZOLE, check with your doctor or pharmacist.

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

HOW TO STORE IT

- Store in a dry place at controlled room temperature (15-30°C). Protect from moisture.
- Do not keep ESOMEPRAZOLE in the bathroom medicine cabinet or other warm moist places.
- Keep ESOMEPRAZOLE well out of reach of children.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist in all cases	Stop taking drug and call your doctor or pharmacist
Rare (frequency of greater than or equal to 1 in 10 000 patients but less than 1 in 1000 patients)		
skin reactions (such as rash, dermatitis, itching and/or hives)	X	
blurred vision	X	X
depression	X	
confusion	X	
shortness of breath	X	
inflammation in the mouth	X	
severe allergic reaction (such as swelling or anaphylactic reaction/shock)	X	X
muscle pain	X	
blood disorders (reduced number of cells in the blood, low blood sodium)†	X	
inflammation of liver (skin and eyes appear yellow)	X	X
gastrointestinal fungal infection	X	
photosensitivity	X	
sore joints	X	
feeling ill	X	
Very Rare (frequency of less than 1 in 10 000 patients)		
severe skin disorders (blisters, ulcers and/or lesions)	X	X
aggression	X	
hallucinations	X	
severely impaired liver function	X	
decreased consciousness	X	
inflammation of the kidney	X	
muscular weakness	X	
development of breasts in males	X	

†These would only be seen if a blood test were taken.

REPORTING SUSPECTED SIDE EFFECTS

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

- Report online at www.healthcanada.gc.ca/medeffect
 - Call toll-free to 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 0701C
Ottawa, ON K1A 0K9
- Postage paid labels, Canada Vigilance 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, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional. This leaflet 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. This leaflet was prepared by Pro Doc Ltée, Laval, Québec, H7L 3W9

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