

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

PrESOMEPRAZOLE

Esomeprazole Magnesium Delayed Release Tablets

20 mg and 40 mg esomeprazole (as esomeprazole magnesium amorphous)

Read this carefully before you start taking ESOMEPRAZOLE 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 ESOMEPRAZOLE.

What is ESOMEPRAZOLE used for?

ESOMEPRAZOLE is used in adults to treat problems caused by too much acid in the stomach such as:

- reflux esophagitis (tissue damage caused by the stomach acid and juices moving up the food tube).
- symptoms of reflux disease (e.g. heartburn, backup of stomach contents to the throat).
- duodenal ulcers (sores on the first part of the intestine) caused by a bacterium, *Helicobacter pylori*.
- symptoms of nonerosive reflux disease (NERD), not related to tissue damage of the food pipe such as:
 - a burning feeling that moves up the food pipe (heartburn).
 - a sour or bitter taste moving up to the mouth.
- a rare condition where the stomach produces too much acid (Zollinger-Ellison syndrome).
- ulcers caused by nonsteroidal anti-inflammatory drugs (drugs for pain and sore joints).

ESOMEPRAZOLE is used in children 12-17 years old to treat:

- reflux esophagitis (tissue damage caused by the stomach acid and juices moving up the food tube).
- symptoms of reflux disease (e.g. heartburn, backup of stomach contents to the throat).
- symptoms of nonerosive reflux disease (NERD), not related to tissue damage of the food pipe such as:
 - a burning feeling that moves up the food pipe (heartburn).
 - a sour or bitter taste moving up to the mouth.

How does ESOMEPRAZOLE work?

ESOMEPRAZOLE is a medicine called a proton pump inhibitor (PPI). ESOMEPRAZOLE works by causing less acid to be made in your stomach.

What are the ingredients in ESOMEPRAZOLE?

Medicinal ingredients: esomeprazole magnesium amorphous

Non-medicinal ingredients:

ESOMEPRAZOLE tablet: crosopvidone, diethyl phthalate, hydroxy propyl cellulose, hypromellose, hypromellose phthalate, iron oxide red, macrogol 400, macrogol 4000, macrogol 6000, microcrystalline cellulose, povidone, sodium stearyl fumarate, sugar spheres (sucrose and maize starch), talc, titanium dioxide.

ESOMEPRAZOLE comes in the following dosage forms:

ESOMEPRAZOLE is available in 20 mg & 40 mg Tablets.

Do not use ESOMEPRAZOLE if:

- you are allergic to the active ingredient esomeprazole magnesium, substituted benzimidazoles or any of the other ingredients of ESOMEPRAZOLE (see **What are the ingredients in ESOMEPRAZOLE?**). If you think you may be allergic, ask your doctor for advice.
- you are taking rilpivirine.

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

- have had any health problems in the past.
- have 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.
 - black (blood-stained) stools.
- are pregnant or trying to become pregnant.
- are breastfeeding or planning to breastfeed.
- are due to have a specific blood test (Chromogranin A).

Other warnings you should know about:

ESOMEPRAZOLE is not recommended for use in patients under 1 year of age.

This medicine should be used at the lowest dose and for the shortest time suitable for your condition. Talk to your doctor if you have any concerns about your treatment.

Treatment in combination with antibiotics:

If you experience symptoms such as severe (bloody or repeated watery) diarrhea, with or without fever, abdominal pain or tenderness, you may have bowel inflammation caused by a bacterial infection (*Clostridium difficile*). If this happens, stop taking the drug combination and call your healthcare professional immediately.

Long-term use of PPIs may interfere with the absorption of Vitamin B12 from the diet. This may cause a shortage of Vitamin B12 in your body. Talk to your doctor about this risk.

Long-term use of PPIs may lead to low blood magnesium in some people. When blood magnesium is lower than normal, it may also lead to low blood calcium and low blood potassium.

Using PPIs for a long time (every day for a year or longer) may increase risks of broken bones of the hip, wrist or spine. Talk to your doctor about this risk.

Using ESOMEPRAZOLE for a long period of time may cause a growth in your stomach (polyp) especially after one year.

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 ESOMEPRAZOLE:

- drugs used to prevent blood clotting (warfarin or coumarin derivatives, clopidogrel). Speak to your doctor or pharmacist if you are taking any of these drugs. Use of ESOMEPRAZOLE with clopidogrel should be avoided.
- medication for HIV: ESOMEPRAZOLE may decrease the effectiveness of some drugs used for HIV treatment; atazanavir, nelfinavir, and saquinavir should not be used with ESOMEPRAZOLE .
- a high dose of methotrexate (a drug used in high doses to treat cancer): ESOMEPRAZOLE may need to be temporarily withdrawn.
- 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), drugs to speed up stomach emptying (cisapride*), transplant rejection (tacrolimus), poor circulation in the legs (cilostazol*), heart problems (digoxin), treatment for tuberculosis (rifampin), St John's Wort (*Hypericum perforatum*) or a certain type of anticancer drug (erlotinib or any other anticancer drug from the same class). However, none of these interactions have been shown to change the effectiveness of esomeprazole magnesium or the other drug.

Drug interactions can be different if you take ESOMEPRAZOLE for short periods of time than if you take it every day.

* not marketed in Canada

How to take ESOMEPRAZOLE:

Follow your doctor's directions carefully. They may be different from the information contained in this leaflet.

- Take all doses of ESOMEPRAZOLE that your doctor prescribes even when you or your child feel well. In some cases, doses every day are needed to control pain and symptoms, to correct acid problems and to help damaged areas heal.
- If you take ESOMEPRAZOLE with antibiotic drugs, it is important that you take all medications twice each day. Take them at the right time each day for one week. Studies have shown that patients who take their medications as prescribed have better ulcer healing rates and greater success getting rid of their *H. pylori* infection.

- Take ESOMEPRAZOLE until your doctor tells you to stop. Even if you start to feel better in a few days, your symptoms may return if ESOMEPRAZOLE is stopped too soon. ESOMEPRAZOLE needs to be taken for the full treatment duration to help correct acid problems.
- ESOMEPRAZOLE may be taken with food or on an empty stomach.

Tablets:

The tablet may be swallowed whole with water. It may also be put in half a glass of water where it will break apart. This will make it easier to swallow. Be sure to swallow all the tiny pellets that come out of the tablet without chewing them. Don't let the pellets sit in water for more than 30 minutes before drinking them. After drinking, rinse the glass with water and drink this as well.

Usual dose:

Adults

Your doctor may tell you to take ESOMEPRAZOLE:

- 20 to 40 mg once a day for 2 to 8 weeks.
- Continue taking ESOMEPRAZOLE 20 mg each day. This is to keep your symptoms from coming back.
- In combination with antibiotic drugs for one week to treat ulcers caused by *Helicobacter pylori*. This also helps to reduce the risk of these ulcers from coming back.
 - If your prescription says ESOMEPRAZOLE, you will take ESOMEPRAZOLE with the antibiotics clarithromycin and amoxicillin.
 - Your pharmacist should also give you information on the two antibiotics.

Maintenance Treatment of NERD (on-demand) dose

After first treatment of NERD, your doctor may suggest that you take ESOMEPRAZOLE 20 mg once daily, as needed, if symptoms of heartburn and regurgitation return once in a while. Contact your doctor if your symptoms get worse, won't go away, or if new symptoms arise.

Children (12 –17 years of age)

ESOMEPRAZOLE (esomeprazole magnesium) is not recommended for use in children under 12 years of age.

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

Overdose:

If you think you have taken too much ESOMEPRAZOLE, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using ESOMEPRAZOLE?

Like all medicines, ESOMEPRAZOLE may cause side effects in some people. Side effects are usually mild. They usually go away a short time after starting ESOMEPRAZOLE.

These are not all the possible side effects you may feel when taking ESOMEPRAZOLE. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions. These side effects may not be caused by ESOMEPRAZOLE in your case, but only a doctor can assess this.

Tell your doctor right away if you have any of these symptoms:

- New or worsening joint pain.
- Rash on your cheeks or arms that gets worse in the sun.

If these side effects become bothersome (or last longer than 1-2 days), discuss with your doctor:

Common:

- Nausea.
- Stomach upset.
- Diarrhea.
- Headache.

Uncommon:

- Dry mouth.
- Dizziness.
- Insomnia.
- Feeling of burning/prickliness/numbing.
- Swelling of extremities.
- Feeling sleepy.
- Feeling like you or your surroundings are moving (vertigo).

Rare:

- Taste disorders.
- Nervousness.
- Hair loss.
- Increased sweating.

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 stopping ESOMEPRAZOLE.

Serious side effects and what to do about them			
	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE (≥ 1 in 10 000 patients but < 1 in 1000 patients)			
skin reactions (such as rash, dermatitis, itching and/or hives)		X	
blurred vision		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
muscle pain		X	
blood disorders (reduced number of cells in the blood, low blood sodium) ⁰		X	
inflammation of liver (skin and eyes appear yellow)			X
gastrointestinal fungal infection		X	
photosensitivity		X	
sore joints		X	
feeling ill		X	
VERY RARE (< 1 in 10 000 patients)			
severe skin disorders (blisters, ulcers and/or lesions)			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	
low blood magnesium ⁰ (which may result in low blood calcium and/or low blood potassium)		X	
Inflammation in the gut (leading to diarrhea)		X	

⁰ These would only be seen if a blood test was taken.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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:

- Keep all tablets sealed in the blister strips until it is time for a dose. If you do not, moisture from the air may damage the drug.
- Keep ESOMEPRAZOLE at controlled room temperature (15° C - 30° C).
- Do not keep ESOMEPRAZOLE in the bathroom medicine cabinet or other warm, moist places.
- Do not use ESOMEPRAZOLE after the expiry date marked on the pack.

Keep out of sight and reach of children.

If you want more information about ESOMEPRAZOLE:

- 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 www.sivem.ca, or by calling 1-855-788-3153.

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Date of Revision: June 15, 2021