

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **Myl-Esomeprazole** **Esomeprazole Delayed Release Tablets**

Read this carefully before you start taking **Myl-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 **Myl-Esomeprazole**.

What is Myl-Esomeprazole used for?

Myl-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 foodpipe).
- 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).

Myl-Esomeprazole is used in children 1-17 years old to treat:

- reflux esophagitis (tissue damage caused by the stomach acid and juices moving up the foodpipe).
- 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 Myl-Esomeprazole work?

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

What are the ingredients in Myl-Esomeprazole?

Medicinal ingredients: esomeprazole magnesium trihydrate

Non-medicinal ingredients:

Colloidal silicon dioxide, Crospovidone, Glycerol monostearate, Hydroxypropyl cellulose, Hypromellose, Iron oxide black, Low-substituted hydroxypropyl cellulose, Magnesium stearate, Methacrylic acid – Ethyl acrylate co-polymer (1:1) dispersion 30%, Microcrystalline cellulose, N-butyl alcohol, Polyethylene glycol, Polysorbate 80, Propylene glycol, Shellac glaze, Sodium lauryl sulfate, Sodium stearyl fumarate, Sugar spheres, Talc, Titanium dioxide and Triethyl citrate. The 20 mg strength also includes carnauba wax, iron oxides red and yellow. The 40 mg strength also includes FD&C Yellow #6 aluminum lake, FD&C Red #40 aluminum lake, and FD&C Blue #2 aluminum lake.

Myl-Esomeprazole comes in the following dosage forms:

Myl-Esomeprazole 20 mg tablets come in 100's HDPE bottle.

Myl-Esomeprazole 40 mg tablets come in 100's and 500's HDPE bottle.

Do not use Myl-Esomeprazole if:

- are allergic to esomeprazole, substituted benzimidazoles or any of the other ingredients of Myl-Esomeprazole or component of the container (see **What are the ingredients in Myl-Esomeprazole?**).
- are taking rilpivirine a medicine used to treat HIV infection.

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

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

Other warnings you should know about:

Myl-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 healthcare professional if you have any concerns about your treatment.

Serious Side Effects: Myl-Esomeprazole can cause serious side effects, including:

- **Serious Skin Reactions:** In very rare cases, serious or life-threatening skin reactions have been reported with PPIs, such as Myl-Esomeprazole.
 - Drug reaction with eosinophilia and systemic symptoms (DRESS),
 - Stevens-Johnson Syndrome (SJS),
 - toxic epidermal necrosis (TEN)
 - erythema multiforme
 - acute generalized exanthematous pustulosis (AGEP)

- **Serious Stomach and Intestine Problems:** Myl-Esomeprazole can cause serious stomach and intestine problems. Tell your healthcare professional 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.
 - black (blood-stained) stools.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Antibiotics: If you take antibiotics while taking Myl-Esomeprazole you may:

- experience symptoms such as severe (bloody or repeated watery) diarrhea, with or without fever, abdominal pain or tenderness. These are symptoms of bowel inflammation caused by a bacterial infection (*Clostridium difficile*).

If this happens, stop taking the drug combination and tell your healthcare professional immediately.

Myl-Esomeprazole should not be used in combination with the antibiotic clarithromycin during pregnancy or when breastfeeding, unless your healthcare professional tells you. Clarithromycin may harm your unborn baby or newborn.

Pregnancy: Tell your healthcare professional if you are pregnant or planning to become pregnant. There are specific risks you must discuss with your healthcare professional.

Long term use of Myl-Esomeprazole: Long-term use of Myl-Esomeprazole 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 healthcare professional about this risk.
- 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.
- increase risks of broken bones of the hip, wrist or spine. This is more likely to happen if you use Myl-Esomeprazole every day for a year or longer. Talk to your healthcare professional about this risk.
- 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 Myl-Esomeprazole:

- Medications that prevent blood clots such as, warfarin, acetylsalicylic acid and clopidogrel. Use of Myl-Esomeprazole with clopidogrel should be avoided as it may decrease the effectiveness of clopidogrel.
- Medicines used to treat HIV such as atazanavir, nelfinavir and saquinavir. Myl-Esomeprazole may decrease the effectiveness or increase side effects of some medicines used to treat HIV. Myl-Esomeprazole should not be used with atazanavir, nelfinavir or saquinavir.
- Methotrexate, used in high doses to treat cancer. Your healthcare professional may tell you to stop taking Myl-Esomeprazole temporarily while you are taking methotrexate.
- Medicines used to treat fungal infections such as itraconazole, ketoconazole, and voriconazole
- Diazepam, used to treat anxiety
- Phenytoin, used to treat epilepsy
- Cisapride (not available in Canada), used to help empty the stomach
- Tacrolimus, used to lower the risk of organ rejection
- Cilostazol (not available in Canada), used to treat poor circulation in the legs
- Digoxin, used to treat heart disorders
- Medicines used to treat tuberculosis such as rifampin
- Herbal medicines such as St John's Wort
- Medicines used in cancer therapy such as erlotinib

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

How to take Myl-Esomeprazole:

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

- Take all doses of Myl-Esomeprazole that your healthcare professional 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 Myl-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 *Helicobacter pylori* infection.
- Take Myl-Esomeprazole until your healthcare professional tells you to stop. Even if you start to feel better in a few days, your symptoms may return if Myl-Esomeprazole is stopped too soon. Myl-Esomeprazole needs to be taken for the full treatment duration to help correct acid problems.

Tablets (delayed release):

- Myl-Esomeprazole may be taken with food or on an empty stomach.
- 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 healthcare professional may tell you to take Myl-Esomeprazole:

- 20 to 40 mg once a day for 2 to 8 weeks.
- Continue taking Myl-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.
 - Your pharmacist should also give you information on the two antibiotics.

Maintenance Treatment of NERD (on-demand) Dose

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

Children (12 –17 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, or a person you are caring for, have taken too much Myl-Esomeprazole, contact a 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 Myl-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 Myl-Esomeprazole?

These are not all the possible side effects you may have when taking Myl-Esomeprazole. If you experience any side effects not listed here, tell your healthcare professional.

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

Common side effects include:

- Nausea

- Stomach upset
- Diarrhea
- Headache

Uncommon side effects include:

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

Rare side effects include:

- 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 healthcare professional's instructions when stopping Myl-Esomeprazole.

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	
RARE			
Blood disorders (low white and/or red blood cell count): feeling tired or weak, pale skin, bruising or bleeding for longer than usual if you hurt yourself, fever, chills		✓	
Blurred vision		✓	
Confusion		✓	
Depression		✓	
Feeling ill		✓	
Gastrointestinal fungal infection: diarrhea, vomiting, melena, hemorrhage, abdominal pain, and fever		✓	
Hepatitis (inflammation of			✓

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	
liver): skin and eyes appear yellow			
Myalgia (muscle pain): aching muscles, tenderness or weakness		✓	
Photosensitivity (sensitivity to sunlight): itchy, red skin when exposed to sunlight		✓	
Severe allergic reaction: shortness of breath, chest pain or discomfort, feeling thirsty, urinating less often, less urine or dark urine, swelling or anaphylactic reaction/shock			✓
Shortness of breath		✓	
Skin reactions: rash, dermatitis, itching and/or hives		✓	
Sore joints		✓	
Stomatitis (mouth sores, redness and swelling of the lining of the mouth): inflammation in the mouth		✓	
VERY RARE			
Aggressive behaviour		✓	
<i>Clostridium difficile</i> colitis (bowel inflammation): severe or persistent diarrhea, abdominal pain, nausea and vomiting, fever		✓	
Decreased consciousness		✓	
Gynecomastia: breast enlargement in men (and/or women)		✓	
Hallucinations: seeing or hearing things that are not there		✓	
Hypomagnesemia (low level of magnesium in the blood): abnormal eye movements,		✓	

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	
fatigue, muscle spasms or cramps, muscle weakness, numbness			
Liver failure (serious disturbance of liver function, hepatic failure): yellow colour to skin, whites of the eyes (jaundice), bleeding easily, swollen abdomen, mental disorientation or confusion, sleepiness, coma		✓	
Muscular weakness		✓	
Nephritis (inflammation of the kidney): decreased appetite, difficulty breathing, fatigue, frequent urination, itchiness, nausea, vomiting		✓	
Serious skin reactions: <ul style="list-style-type: none"> • Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish) • Swelling and redness of eyes or face • Flu-like feeling, fever, chills, body aches, swollen glands, cough 			✓
UNKNOWN			
Subacute cutaneous lupus erythematosus: new or worsening joint pain, rash on your cheeks or arms that gets worse in the sun			✓

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:

Keep Myl-Esomeprazole at room temperature (15-30°C).

Protect from moisture, do not keep Myl-Esomeprazole in the bathroom medicine cabinet or other warm, moist places.

Do not use Myl-Esomeprazole after the expiry date marked on the pack.

Keep out of reach and sight of children.

If you want more information about Myl-Esomeprazole:

- 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.mylan.ca, or by calling 1-844-596-9526.

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