

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION¹**

**Pr APO-ESOMEPRAZOLE
Esomeprazole Magnesium**

Read this carefully before you start taking **APO-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 **APO-ESOMEPRAZOLE**.

What is APO-ESOMEPRAZOLE used for?

APO-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).
- 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.
- ulcers caused by nonsteroidal anti-inflammatory drugs (drugs for pain and sore joints).

APO-ESOMEPRAZOLE is used in children 12 to 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 APO-ESOMEPRAZOLE work?

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

What are the ingredients in APO-ESOMEPRAZOLE?

Medicinal ingredients: esomeprazole magnesium

Non-medicinal ingredients (listed in alphabetical order): colloidal silicon dioxide, copovidone, ferric oxide red, ferric oxide yellow, magnesium stearate, methacrylic acid copolymer type C, talc, titanium dioxide and triethyl citrate.

APO-ESOMEPRAZOLE comes in the following dosage forms:

APO-ESOMEPRAZOLE is available as 20 mg and 40 mg tablets.

Do not use APO-ESOMEPRAZOLE if:

- you are allergic to the active ingredient esomeprazole, substituted benzimidazoles or any of the other ingredients of APO-ESOMEPRAZOLE (see **What are the ingredients in APO-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 APO-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:

APO-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.

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 APO-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 APO-ESOMEPRAZOLE with clopidogrel should be avoided.
- medication for HIV: APO-ESOMEPRAZOLE may decrease the effectiveness of some drugs used for HIV treatment; atazanavir, saquinavir and nelfinavir should not be used with APO-ESOMEPRAZOLE.
- a high dose of methotrexate (a drug used in high doses to treat cancer): APO-ESOMEPRAZOLE may need to be temporarily withdrawn.
- Blood levels of some drugs may be influenced if APO-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 APO-ESOMEPRAZOLE or the other drug.

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

* not marketed in Canada

How to take APO-ESOMEPRAZOLE:

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

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

- APO-ESOMEPRAZOLE should be swallowed whole with sufficient water. Do not disperse, divide, crush or chew the tablets.

Usual dose:*Adults*

Your doctor may tell you to take APO-ESOMEPRAZOLE:

- 20 to 40 mg once a day for 2 to 8 weeks.
- Continue taking APO-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 APO-ESOMEPRAZOLE 1-2-3 A[®], you will take APO-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 APO-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)

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 APO-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 APO-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 APO-ESOMEPRAZOLE?

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

These are not all the possible side effects you may feel when taking APO-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 APO-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 APO-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 (≥ 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 magnesium⁰ (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 help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect->

canada/adverse-reaction-reporting.html);

- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

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:

- Product must be stored between 15°C-30°C in a tightly closed container and protected from moisture.
- Do not keep APO-ESOMEPRAZOLE in the bathroom medicine cabinet or other warm, moist places.
- Do not use APO-ESOMEPRAZOLE after the expiry date marked on the pack.
- Keep out of sight and reach of children.

If you want more information about APO-ESOMEPRAZOLE:

- Talk to your healthcare professional
- For questions or concerns contact DISpedia, Apotex's Drug Information Service at 1-800-667-4708.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>; Apotex Inc.'s website, <http://www.apotex.ca/products> or by calling 1-800-667-4708

NOTE: This PATIENT MEDICATION INFORMATION leaflet provides you with the most current information at the time of printing.

This leaflet can also be found at: <http://www.apotex.ca/products>.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9

Last revised: December 22, 2017