

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr **OMEPRAZOLE**

Omeprazole Delayed-Release Capsules

Read this carefully before you start taking **OMEPRAZOLE** 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 **OMEPRAZOLE**.

What is OMEPRAZOLE used for?

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

- stomach ulcers (sores).
- duodenal ulcers (sores on the first part of the intestine).
- stomach and duodenal ulcers caused by a bacterium, *Helicobacter pylori*.
- ulcers caused by nonsteroidal anti-inflammatory drugs (drugs for pain and sore joints).
- 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).
- a rare condition where the stomach produces too much acid (Zollinger-Ellison syndrome).

How does OMEPRAZOLE work?

OMEPRAZOLE is a medicine called a proton pump inhibitor (PPI). OMEPRAZOLE works by reducing the amount of acid made in your stomach.

What are the ingredients in OMEPRAZOLE?

Each OMEPRAZOLE capsule contains omeprazole as the active ingredient. In addition, it contains the following non-medicinal ingredients (listed in alphabetical order): D&C Red No. 28, D&C Red No. 33, D&C Yellow No. 10, eudragit, FD&C Blue No. 1, FD&C Red No. 40, gelatin, magnesium hydroxide, mannitol, povidone, titanium dioxide and triethyl citrate.

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

OMEPRAZOLE comes in the following dosage forms:

Capsules of omeprazole 20 mg

Do not use OMEPRAZOLE if:

- you are allergic to omeprazole, substituted benzimidazoles or any of the other ingredients in OMEPRAZOLE (see "What are the ingredients in OMEPRAZOLE?").
- you are taking rilpivirine

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

- have had any health problems in the past.
- have severe liver problems now or have had in the past.
- are pregnant or plan to become pregnant.
- are breastfeeding or planning to breastfeed, as omeprazole is excreted in breast milk.
- take any other medications, including ones you can buy without a prescription.
- are due to have a specific blood test (Chromogranin A).

Other warnings you should know about:

OMEPRAZOLE is not recommended for use in patients under 18 years 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.

Tell 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.
- black (blood-stained) stools.

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 OMEPRAZOLE 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 OMEPRAZOLE:

- medication for HIV: OMEPRAZOLE may decrease the effectiveness of some drugs used for HIV treatment; atazanavir, nelfinavir, and saquinavir should not be used with OMEPRAZOLE.

- a high-dose of methotrexate (a drug used in high doses to treat cancer): OMEPRAZOLE may need to be temporarily withdrawn.
- clopidogrel, which is used for the prevention of blood clots: OMEPRAZOLE may interact with this drug, therefore use with clopidogrel should be avoided.
- Drug effects may be influenced if OMEPRAZOLE is taken at the same time as some drugs used to prevent fungal infections (itraconazole, ketoconazole, voriconazole), anxiety (diazepam), epilepsy (phenytoin), blood clotting (warfarin or other vitamin K blockers), 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).

* not marketed in Canada

How to take OMEPRAZOLE:

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

- Take all doses of OMEPRAZOLE that your doctor prescribes even when you feel well. Doses every day are needed to help damaged areas heal.
- If you take OMEPRAZOLE with antibiotic drugs, it is important that you take all medications at the right time of day for the whole treatment period. 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 OMEPRAZOLE until your doctor tells you to stop. Even if you start to feel better in a few days, your symptoms may return if OMEPRAZOLE is stopped too soon. OMEPRAZOLE needs to be taken for the full treatment to help correct acid problems.
- OMEPRAZOLE may be taken with food or on an empty stomach.
- Do not chew or crush your OMEPRAZOLE capsules. Swallow the capsule whole with half a glass of water.

Usual dose:

Your doctor may tell you to take OMEPRAZOLE:

- 10 to 40 mg once a day for 2 to 8 weeks to heal damaged areas.
- 10 to 40 mg to control symptoms of reflux disease or to stop reflux esophagitis from coming back.
- 20 mg to stop ulcers from returning while you take your medicine for pain and joint problems.
- 60 mg once a day to treat Zollinger-Ellison syndrome.
- In combination with antibiotic drugs for one week to treat ulcers caused by *Helicobacter pylori*, your doctor may prescribe:
 - omeprazole, clarithromycin and amoxicillin Triple Therapy
 - OR
 - omeprazole, clarithromycin and metronidazole Triple Therapy
 - Take the 3 drugs two times a day for one week.
 - If your ulcer is bothering you, your doctor may recommend further treatment with OMEPRAZOLE to make sure that your ulcer is healed.

Overdose:

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

Missed Dose:

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

What are possible side effects from using OMEPRAZOLE?

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

These are not all the possible side effects you may feel when taking OMEPRAZOLE. 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 OMEPRAZOLE 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.

Common side effects (≥ 1 in 100 patients):

- Headache.
- Diarrhea.
- Constipation.
- Abdominal pain.
- Nausea/ vomiting.
- Excess gas in stomach (flatulence).

Uncommon side effects (≥ 1 in 1000 patients, but < 1 in 100 patients):

- Dizziness.
- Feeling like you or your surroundings are moving (vertigo).
- Difficulty sleeping.
- Feeling sleepy.
- Sensation of burning/ prickling/ numbness.

Rare side effects (< 1 in 1000 patients):

- Dry mouth.
- Hair loss.
- Increased sweating.
- Taste disorders.

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 OMEPRAZOLE.

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	
UNCOMMON (≥ 1 in 1000 patients, but < 1 in 100 patients)			
skin reactions (such as skin rash, dermatitis, itchy skin and/or hives)		X	
feeling ill		X	
RARE (≥ 1 in 10 000 patients, but < 1 in 1000 patients)			
inflammation in the mouth		X	
gastrointestinal fungal infection		X	
inflammation of the kidney		X	
liver problems, ie, inflammation of the liver with or without jaundice, impaired liver function			X
blood disorders (reduced number of cells in the blood, low blood sodium)		X	
inflammation in the gut (leading to diarrhea)		X	
sore joints and muscles		X	
muscular weakness		X	
development of breasts in males		X	
sensitivity to sunlight		X	
severe skin reactions			X
hypersensitive (allergic) reactions (such as swelling of tissues, fever, discomfort/ tightness in chest and anaphylactic shock)			X
blurred vision		X	
if you already have severe liver disease, you may experience disorientation/ aggression/ confusion/ decreased consciousness		X	
if you are very ill, you may feel confused, nervous, depressed or hallucinate		X	
VERY RARE (< 1 in 10 000 patients)			
low blood magnesium ^o (which may result in low blood calcium and/or low blood potassium)		X	

^o 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. Other situations may

arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using OMEPRAZOLE.

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 all capsules in their container until it is time for a dose. If you do not, moisture from the air may damage the capsules.

Remember to keep OMEPRAZOLE well out of reach of children. OMEPRAZOLE should be stored at room temperature (15 °C to 30°C), in tightly closed and moisture resistant containers. Do not keep OMEPRAZOLE in the bathroom medicine cabinet or other warm, moist places.

Do not use OMEPRAZOLE after the expiry date marked on the pack.

If you want more information about OMEPRAZOLE:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Patient Medication Information on the manufacturer's website <http://www.sanis.com> or by contacting Sanis Health Inc. at:

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