

PART III: CONSUMER INFORMATION

OMEPTM
Omeprazole delayed-release capsules 20 mg



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

ABOUT THIS MEDICATION

What the medication is used for:

OMEPTM is recommended for adults (18 years and older) to relieve frequent heartburn – when you have heartburn 2 or more days a week.

Heartburn is a painful burning feeling in the chest which rises up to the throat.

OMEPTM is not the right medicine for you if you suffer from heartburn once a week or less, or if you want immediate relief.

What it does:

OMEPTM belongs to a group of medicines called Proton pump inhibitors which work by reducing the amount of acid the stomach makes.

OMEPTM works differently from other nonprescription heartburn products, such as antacids and other acid reducers. OMEPTM stops acid production at the source, the acid pump inside your stomach that produces acid.

Although OMEPTM will start to suppress acid within a few hours, it is not intended to give instant relief. You may have to wait 3 to 5 days to feel the full effect of the product on heartburn symptoms, although some people get complete relief of symptoms within 24 hours. Make sure you take the capsules for all 14 days even if you start to feel better.

What else can you do to help avoid your symptoms?

- Avoid or limit foods such as: caffeine, chocolate, spicy or fatty foods, and alcohol.
- Eat smaller, more frequent meals. Avoid eating or drinking late at night or 2-3 hours before bedtime.
- Avoid lying down or bending over soon after eating.
- Try to reduce stress.
- If you are overweight, try to reduce excess weight.
- If you smoke, try to stop smoking or reduce the amount you smoke.

When it should NOT be used:

You should not take OMEPTM if you think you might be allergic to omeprazole or any of the ingredients (see "What the medicinal ingredients are:").

What the medicinal ingredient is:

The medicinal ingredient is omeprazole.

What the nonmedicinal ingredients are:

Each 20 mg capsule contains the nonmedicinal ingredients: carrageenan, croscarmellose sodium, dibutyl sebacate, hypromellose, hypromellose phthalate, iron oxide red, lactose anhydrous, low-substituted hydroxypropyl cellulose, microcrystalline cellulose, polysorbate 80, potassium chloride, povidone, talc, titanium dioxide, water.

What dosage forms it comes in:

OMEPTM is available in capsules containing 20 mg of omeprazole.

WARNINGS AND PRECAUTIONS

Warnings. Do not use if:

- You have trouble or pain swallowing food; have bloody, black stools or are vomiting blood.
- You have been having frequent heartburn for over 3 months. These may be signs of a more serious condition. You may need different treatment. See your doctor immediately.

OMEPTM may decrease the efficacy of some drugs used for HIV treatment (**atazanavir** and **nelfinavir**) or heart disease (**clopidogrel**); these drugs should not be used with OMEPTM.

BEFORE you use OMEPTM, talk to your doctor or pharmacist if:

- you are taking any other medicines to reduce stomach acid
- you have heartburn with lightheadedness, sweating or dizziness
- you have chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders
- you have frequent wheezing, particularly with heartburn
- you have unexplained weight loss
- you have nausea or vomiting
- you have stomach pain
- you have jaundice or other liver problems
- you now have or in the past have had a gastric ulcer or surgery on your stomach or bowels
- you are pregnant, plan to become pregnant, or are breastfeeding

STOP USE and ask your doctor if:

- you have severe and/or persistent diarrhea
- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment within a 4-month period

INTERACTION WITH THIS MEDICATION

Drugs that may interact with OMEPTM include the following. Ask your doctor or pharmacist before use if you are taking:

- Atazanavir, Nelfinavir (medicines for HIV infection)
- Cilostazol (a medicine to treat leg pain)
- Clarithromycin, Erythromycin (antibiotics)
- Clopidogrel (a heart medicine)
- Diazepam (an anxiety medicine)
- Digoxin (a heart medicine)
- Erlotinib (a medicine against cancer) or any other anticancer drug from the same class
- Ketoconazole, Itraconazole, Voriconazole (antifungal or anti-yeast medicines)
- Methotrexate (a medicine used against cancer)
- Phenytoin (an epilepsy medicine)
- St. John's Wort (*Hypericum perforatum*)
- Tacrolimus (an immune system medicine)
- Warfarin (a blood-thinning medicine)

* not marketed in Canada

PROPER USE OF THIS MEDICATION

Usual Dose: Adults (18 years of age and older)

14-Day Course of Treatment

- Take 1 capsule with a glass of water, before eating in the morning.
- Do NOT chew or crush capsules. This decreases how well OMEPTM works.
- Do NOT take more than 1 capsule every 24 hours.
- Take every day for 14 days.
- Do NOT use for more than 14 days unless directed by your doctor.
- Do NOT repeat a 14-day course of treatment within a period of 4 months unless directed by your doctor.

When to take OMEPTM Again:

You should wait at least 4 months before taking another 14-day course of treatment.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of OMEPTM 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 capsule. Just take your next dose on time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

OMEPTM may cause side effects in some people. Side effects are usually mild and go away a short time after starting OMEPTM. Common side effects that may occur: cold or flu-like symptoms, diarrhea, excess gas, headache, nausea or vomiting, stomach pain.

Uncommon side effects that may occur: altered liver values, dizziness, feeling of burning/prickliness/numbness of the skin, feeling sleepy, insomnia, itching, skin rash.

Other unwanted effects may occur in rare cases. If you experience any bothersome or unusual effects while using OMEPTM, check with your doctor or pharmacist right away.

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

Symptoms/Effects	Talk with your doctor or pharmacist	Stop taking drug and call your doctor or pharmacist
Rare (frequency of greater than or equal to 1 in 10,000 but less than 1 in 1,000 patients)		
Blurred vision		3
Confusion	3	
Depression	3	
Development of breasts in men	3	
Hallucinations	3	
Impaired liver function (skin and eyes appear yellow)		3
Inflammation in the mouth	3	
Muscle pain	3	
Muscle weakness	3	
Restlessness	3	
Severe allergic reaction (such as swelling or anaphylactic reaction/shock)		3
Severe skin reaction (rash with swelling, blisters and peeling of the skin, ulcers, often with high fever)		3
Sore joints	3	
Very Rare (frequency of less than 1 in 10,000 patients)		
Ear problems (pain, hearing loss, ringing sounds)		3
Eye problems (edema, pain)		3
Impotence	3	
Vertigo	3	

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

HOW TO STORE IT

OMEPTM (omeprazole) 20 mg capsules are two-piece hard gelatin capsules with a dark pink cap, pink body, each imprinted with "OME 20".

Store blister packs at room temperature 15–30°C. Protect from moisture.

Keep OMEPTM out of reach of children.

Do not keep OMEPTM in the bathroom medicine cabinet or other warm, moist places.

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

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;
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

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.

MORE INFORMATION

This document, plus the full product monograph prepared for health professionals, can be obtained by contacting the sponsor, **Sandoz Canada Inc.**, at: 1-800-361-3062

Or by written request at:

145, Jules-Léger,
Boucherville, Québec
J4B 7K8 Canada

Or by e-mail at: medinfo@sandoz.com

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Sandoz Canada Inc.
Boucherville (Québec)
J4B 7K8 Canada
medinfo@sandoz.com
1-800-361-3062

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