

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

 LOSEC®
omeprazole delayed release capsules

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

What is LOSEC used for?

LOSEC 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 LOSEC work?

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

What are the ingredients in LOSEC?

Medicinal ingredients: omeprazole

Non-medicinal ingredients: disodium hydrogen phosphate dihydrate, gelatin, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose anhydrous, magnesium stearate, mannitol, methacrylic acid copolymer, microcrystalline cellulose, polyethylene glycol and sodium lauryl sulphate.

The capsule shells also contain iron oxide and titanium dioxide as colouring agents.

LOSEC comes in the following dosage forms:

Capsules of omeprazole 20 mg

Do not use LOSEC if:

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

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LOSEC. 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:

LOSEC 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 LOSEC 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 LOSEC:

- medication for HIV: LOSEC may decrease the effectiveness of some drugs used for HIV treatment; atazanavir, nelfinavir, and saquinavir should not be used with LOSEC.
- a high-dose of methotrexate (a drug used in high doses to treat cancer): LOSEC may need to be temporarily withdrawn.
- clopidogrel, which is used for the prevention of blood clots: LOSEC may interact with this drug, therefore use with clopidogrel should be avoided.
- Drug effects may be influenced if LOSEC 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 LOSEC:

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

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

Usual dose:

Your doctor may tell you to take LOSEC:

- 20-40 mg once a day for 2-8 weeks to heal damaged areas.
- 20-40 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*.
 - as Omeprazole, Amoxicillin and Clarithromycin Triple Therapy: The recommended dose for eradication of *H. pylori* is LOSEC 20 mg, amoxicillin 1000 mg and

clarithromycin 500 mg, all twice daily for seven days.

- or as Omeprazole, Metronidazole and Clarithromycin Triple Therapy: The recommended dose for eradication of *H. pylori* is LOSEC 20 mg, metronidazole 500 mg and clarithromycin 250 mg, all twice daily for seven days.
- If your ulcer is bothering you, your doctor may recommend further treatment with LOSEC to make sure that your ulcer is healed.

Overdose:

If you think you have taken too much LOSEC, 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 LOSEC 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 LOSEC?

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

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

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/		X	

aggression/ confusion/ decreased consciousness			
if you are very ill, you may feel confused, nervous, depressed or hallucinate		X	
VERY RARE (< 1 in 10 000 patients)			
low blood magnesium ^θ (which may result in low blood calcium and/or low blood potassium)		X	

^θ 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 LOSEC.

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 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.

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:

LOSEC comes in a container with a drying agent. 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.

Keep the package at room temperature (15-30°C). Do not keep LOSEC in the bathroom medicine cabinet or other warm, moist places.

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

Keep out of sight and reach of children.

If you want more information about LOSEC:

- 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, the Xediton Pharmaceuticals Inc. website: www.xediton.com, or by calling Xediton Pharmaceuticals Inc. at: 1-888-XEDITON (933-4866).

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

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This leaflet was prepared by CHEPLAPHARM Arzneimittel GmbH, Germany.

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Last Revised: October 30, 2020