

## INFORMATION FOR THE CONSUMER

### IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT

 LOSEC

(omeprazole magnesium delayed release tablets)

Read this leaflet carefully. It contains general points about LOSEC and should add to more specific advice from your doctor or pharmacist.

#### **WHAT IS LOSEC USED FOR AND HOW DOES IT WORK?**

LOSEC is the brand name for a drug called omeprazole.

The most common uses of LOSEC are:

- for stomach ulcers or for duodenal ulcers, including ulcers caused by infection with a bacterium called *Helicobacter pylori*;
- for ulcers caused by your medicine for pain and joint problems (NSAID-associated gastric and duodenal ulcers);
- for gastroesophageal reflux disease and its symptoms such as: a burning sensation rising from the chest towards the neck (heartburn) and the flow of bitter/sour juice into the mouth (regurgitation);
- and for dyspepsia, a group of symptoms which may include stomach pain/discomfort, heartburn and regurgitation. Dyspepsia can be caused by the other conditions in this list.

LOSEC may also be used in rare conditions like “Zollinger-Ellison syndrome,” where the stomach produces large amounts of acid. LOSEC works by reducing the amount of acid made in your stomach. This helps in treating acid-related and bacteria-related stomach problems.

Your doctor will have explained why you are being treated with LOSEC and will have told you what dose to take. Follow those directions carefully. They may differ from the information contained in this leaflet.

#### **WHAT IS IN LOSEC?**

Each LOSEC tablet contains omeprazole magnesium as the active ingredient. In addition, it contains the following non-medicinal ingredients (listed in alphabetical order): hydroxypropyl methylcellulose, iron oxide, mannitol, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol, sodium starch glycolate, sodium stearyl fumarate, talc and titanium dioxide.

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

## WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING LOSEC?

Tell your doctor

- about **all** health problems you have now or have had in the past;
- about severe liver problems you have now or have had in the past;
- about other medicines you take, including ones you can buy without a prescription. 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);
- if you are taking medication for HIV. LOSEC may decrease the effectiveness of some drugs used for HIV treatment; atazanavir and nelfinavir should not be used with LOSEC;
- if you are taking a high-dose of methotrexate (a drug used in high doses to treat cancer). LOSEC may need to be temporarily withdrawn;
- if you are taking clopidogrel, which is used for the prevention of blood clots. LOSEC may interact with this drug, therefore use with clopidogrel is not recommended;
- if you are pregnant, plan to become pregnant or are breastfeeding.

\*not marketed in Canada

## WHEN SHOULD LOSEC NOT BE USED?

If you are allergic to omeprazole or any of the other ingredients in LOSEC (see "What is in LOSEC?").

## HOW DO I TAKE LOSEC PROPERLY?

Take all doses of LOSEC, as recommended by your doctor, even when you feel well. Daily doses are needed to help damaged areas heal. In general, the recommended dose for treating acute disease is 10-40 mg once a day for 2-8 weeks. Your doctor may recommend that you continue taking LOSEC 10-40 mg to control symptoms of reflux disease or to prevent reflux esophagitis from coming back, or LOSEC 20 mg to prevent ulcers from returning while you continue to take your medicine for pain and joint problems.

LOSEC may be used in combinations which include clarithromycin, amoxicillin and/or metronidazole (antibiotic drugs) for one week to treat ulcers caused by *Helicobacter pylori*. Your prescription may say Losec 1-2-3 A<sup>®</sup> or Losec 1-2-3 M<sup>®</sup>. This tells the pharmacist to give you three different drugs (LOSEC and two antibiotics), for you to take two times a day for one week. If your ulcer is bothering you, your doctor may recommend further treatment with LOSEC to make sure that your ulcer is healed.

If you are given LOSEC in combination with antibiotic drugs, it is important that you take all medications at the correct time of day and for the entire treatment period, to ensure they will

work properly. 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 duration of treatment to help correct acid problems.

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 tablet. Do not double the dose. Just take your next dose on time.

LOSEC may be taken with food or on an empty stomach.

### **HOW DO I USE THE LOSEC COMPLIANCE PACK?**

There are 14 days of labelled tablets, with one extra to make 15. All 15 tablets, including the one labelled "Take this tablet last", are exactly the same. Once you have finished the 14 labelled tablets in the blister pack, take the one marked "Take this tablet last" before starting your next blister pack.

To treat ulcers caused by *Helicobacter pylori*, take one 20 mg tablet from each row (2 tablets per day) that match the day you begin the pack.

### **ARE THERE ANY SIDE EFFECTS?**

Like any medication, LOSEC may cause side effects in some people. Side effects that do occur are usually mild and go away a short time after starting LOSEC.

Talk with your doctor if you suffer from any of these effects or if you get any other unusual or unexpected symptoms. These side effects may not be caused by LOSEC in your case, but only a doctor can assess this.

Common side effects that may occur (frequency of greater than or equal to 1 in 100 patients):

- Headache, diarrhoea, constipation, abdominal pain, nausea/ vomiting, and excess gas in stomach (flatulence).

Uncommon side effects that may occur (frequency of greater than or equal to 1 in 1000 patients, but less than 1 in 100 patients):

- Dizziness, sensation of movement of one's self or of one's surroundings (vertigo), difficulty sleeping, feeling sleepy, sensation of burning/ prickling/ numbness, skin reactions (such as skin rash, dermatitis, itchy skin and/or hives) and feeling ill.

Rare side effects that may occur (frequency of less than 1 in 1000 patients):

- Dry mouth, inflammation in the mouth, gastrointestinal fungal infection, kidney and liver problems (i.e., inflammation of the kidney, inflammation of the liver with or without jaundice, impaired liver function), blood disorders (reduced number of cells in the blood, low blood sodium), inflammation in the gut (leading to diarrhea), sore joints and muscles, muscular weakness, development of breasts in males, sensitivity to sunlight, severe skin reactions, hair loss, hypersensitive (allergic) reactions (such as swelling of tissues, fever, discomfort/ tightness in chest and anaphylactic shock), increased sweating, blurred vision, and taste disorders. If you already have severe liver disease, you may experience disorientation/ aggression/ confusion/ decreased consciousness. If you are very ill, you may feel confused, nervous, depressed or hallucinate.

Very rare side effects that may occur (frequency of less than 1 in 10000 patients) include low blood magnesium.

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 call your doctor or pharmacist immediately and stop taking the drug combination.

Other unwanted effects, which cannot be predicted, may occur in rare cases. If you experience any bothersome or unusual effects while using LOSEC, check with your doctor or pharmacist right away.

### **WHAT SHOULD I DO IN CASE OF OVERDOSE?**

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.
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No severe symptoms have been seen in patients who have taken doses up to 400 mg.

### **WHERE SHOULD I KEEP LOSEC?**

Keep all tablets sealed in the blister strips until it is time for a dose. If you do not, moisture from the air may damage the tablets.

Remember to keep LOSEC well out of reach of children. Keep the compliance pack 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.

### **Important Note:**

This leaflet alerts you to some of the times you should call your doctor. If you experience symptoms that may indicate a more serious stomach or intestinal problem, you should contact

your doctor immediately. Such symptoms may include any of the following: difficulty swallowing, unintentional weight loss, vomiting blood or food, or black (blood-stained) stools. Other situations, which cannot be predicted, 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.

**NOTE:** This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing. Please refer to the Consumer Information Leaflet located at [www.astrazeneca.ca](http://www.astrazeneca.ca), to see if more up-to-date information has been posted.

For additional information on acid-related diseases, please call 1 800 668-6000.

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