

## INFORMATION FOR THE CONSUMER

### IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT

 LOSEC MUPS™

(omeprazole magnesium delayed release tablets)

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

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

LOSEC MUPS is the brand name for a drug called omeprazole.

The most common uses of LOSEC MUPS 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 reflux esophagitis (tissue damage caused by stomach contents flowing back up the food pipe);
- 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 MUPS may also be used in rare conditions like “Zollinger-Ellison syndrome,” where the stomach produces large amounts of acid. LOSEC MUPS 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 MUPS?**

Each LOSEC MUPS tablet contains omeprazole as the active ingredient. In addition, it contains the following non-medicinal ingredients (listed in alphabetical order): glyceryl monostearate, hydroxypropylcellulose, hydroxypropyl methylcellulose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol, polysorbate, polyvinylpyrrolidone crosslinked, sodium stearyl fumarate, sugar spheres, talc, titanium dioxide and triethyl citrate.

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 MUPS?**

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) and in transplant patients (tacrolimus);
- 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 pregnant, plan to become pregnant or are breastfeeding.

## **WHEN SHOULD LOSEC MUPS NOT BE USED?**

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

## **HOW DO I TAKE LOSEC MUPS PROPERLY?**

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

LOSEC MUPS may be used in combination therapy with antibiotic drugs for one week to treat ulcers caused by *Helicobacter pylori*. Your prescription may say Losec 1-2-3 A<sup>®</sup> (which includes clarithromycin and amoxicillin) or Losec 1-2-3 M<sup>®</sup> (which includes clarithromycin and metronidazole). This tells the pharmacist to give you three different drugs (LOSEC MUPS 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 MUPS to make sure that your ulcer is healed.

If you are given LOSEC MUPS 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 MUPS until your doctor tells you to stop. Even if you start to feel better in a few days, your symptoms may return if LOSEC MUPS is stopped too soon. LOSEC MUPS needs to be taken for the full duration of treatment to help correct acid problems.

If you miss a dose of LOSEC MUPS 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 MUPS may be taken with food or on an empty stomach.

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

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

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 MUPS 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), 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.

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

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

Call your doctor, pharmacist or regional poison control centre right away in case of an overdose. However, no severe symptoms have been seen in patients who have taken doses up to 400 mg.

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

Keep all LOSEC MUPS tablets in the original container until it is time for a dose. If you do not, moisture from the air may damage the LOSEC MUPS tablets.

Remember to keep LOSEC MUPS well out of reach of children. Store at room temperature (15-30 °C). Do not keep LOSEC MUPS in the bathroom medicine cabinet or other warm, moist places.

Do not use LOSEC MUPS after the expiry date marked on the container.

### **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 MUPS.

**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.

LOSEC MUPS™, LOSEC 1-2-3 A®, LOSEC 1-2-3 M® and the AstraZeneca logo are trademarks of the AstraZeneca group of companies.

AstraZeneca Canada Inc.  
Mississauga, ON  
L4Y 1M4

©AstraZeneca 2000, 2005

Last Revised: December 3, 2008