

Patient Information Leaflet

SCHEDULING STATUS: S4

LOSEC MUPS® 10, LOSEC MUPS® 20, LOSEC MUPS® 40, Film-coated Tablets

Omeprazole

Contains sugar: sugar spheres (0,250 – 0,355) 22 mg per 10 mg tablet; (0,250 – 0,355) 22 mg per 20 mg tablet; (0,250 – 0,355) 45 mg per 40 mg tablet

Read all of this leaflet carefully before you start taking LOSEC MUPS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LOSEC MUPS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LOSEC MUPS is and what it is used for
2. What you need to know before you take LOSEC MUPS
3. How to take LOSEC MUPS
4. Possible side effects
5. How to store LOSEC MUPS
6. Contents of the pack and other information

1. What LOSEC MUPS is and what it is used for

LOSEC MUPS is a type of medicine called a “proton pump inhibitor” which reduces the production of acid in your stomach.

It is used to treat the following conditions:

Adults:

- ulcers in the upper part of the intestine (duodenal ulcer)
- stomach ulcers (gastric ulcer)
- stomach ulcers or duodenal ulcers caused by medicines for pain and joint inflammation (NSAID associated gastric and duodenal ulcers or erosions)
- ulcers, which are infected with bacteria, called *Helicobacter pylori*
- inflammation of the gullet caused by a return flow of fluid from the stomach (reflux oesophagitis)
- disease with symptoms caused by a return flow of fluid from the stomach (symptomatic gastro-oesophageal reflux disease)
- acid-related upper abdominal pain or discomfort (acid related dyspepsia)
- hormone-producing tumours in the pancreas causing excess acid in the stomach (Zollinger-Ellison syndrome).

Children:

- For the short term (up to 3 months) treatment of severe ulcerative oesophagitis, which has not responded to previous medical treatment.

Severe ulcerative reflux oesophagitis is an inflammation of the oesophagus (gullet), including the development of ulcers on the lining of the gullet, caused by stomach acid flowing back into the gullet.

2. What you need to know before you take LOSEC MUPS

Do not take LOSEC MUPS

- if you are hypersensitive (allergic) to omeprazole, substituted benzimidazoles, or any of the other ingredients of LOSEC MUPS (listed in section 6).
- if you are allergic to other “proton pump inhibitors” or any of the other ingredients of LOSEC MUPS.

Warnings and precautions

Take special care with LOSEC MUPS:

- If you are taking LOSEC MUPS at the same time as some medicines for HIV, such as atazanavir

and nelfinavir, as it is not recommended.

- If you notice any of the following:
 - weight loss without trying to lose weight
 - you begin to vomit blood or food
 - pain or indigestion during treatment with LOSEC MUPS
 - you pass black (blood-stained) stools. You should contact your doctor immediately.
- If you have kidney problems. LOSEC MUPS can cause a kidney problem called acute interstitial nephritis (AIN) at any time during treatment. If you notice a decrease in the quantity of your urine, or you have blood in your urine, contact your doctor right away.
- If you are using a certain type of anti-cancer medicine (such as erlotinib or another anti-cancer medicine from the same class).
- If you have severe liver problems. Your doctor may want to reduce the dosage.
- If you are due to have a specific blood test (Chromogranin A).
- If you start suffering from stomach infections and runny tummy.
- If you are feeling tired, confused, dizzy, have an irregular heartbeat and seizures/fits. This may be due to a lack of magnesium in your blood. You may need to take a magnesium replacement and discontinue your LOSEC MUPS.
- If you are taking a heart medicine called digoxin, or other medicines which may decrease your magnesium levels.

Some population studies have indicated that the use of proton pump inhibitors (like LOSEC MUPS) may be associated with an increased risk of osteoporotic bone fractures (osteoporosis is a condition where certain bones become brittle). Please inform your doctor if you have been diagnosed with osteoporosis (brittle bone disease).

Serious skin reactions have occurred in patients taking omeprazole, as in LOSEC MUPS. The rash can involve ulcers in the mouth throat, nose, genitals and conjunctivitis (swollen red eye). These serious skin reactions often occur after flu-like symptoms such as fever, headache and body ache. The rash

may cover large parts of the body with blistering and peeling of the skin. If you develop a rash or any of these skin symptoms, even after several weeks, stop taking LOSEC MUPS and contact your doctor immediately

If you get a rash on your skin, especially in areas exposed to the sun, tell your doctor as soon as you can, as you may need to stop your treatment with LOSEC MUPS. Remember to also mention any other ill effects like pain in your joints.

Other medicines and LOSEC MUPS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Tell your doctor or pharmacist:

- if you are taking any of the following medicines used to prevent or treat:
 - fungal infections (itraconazole, ketoconazole, voriconazole, posaconazole)
 - anxiety (diazepam)
 - epilepsy (phenytoin)
 - blood clotting (warfarin or other vitamin K blockers or clopidogrel)
 - intermittent claudication (cilostazol)
 - transplant rejection (tacrolimus)
 - HIV (atazanavir, nelfinavir or saquinavir)
 - heart problems (digoxin)
 - tuberculosis (rifampicin)
 - depression (St John's Wort / *Hypericum perforatum*)
- if you are using a certain type of anti-cancer medicine (such as erlotinib or another anti-cancer medicine from the same class)
- if you are taking LOSEC MUPS at the same time as some medicines for HIV, such as atazanavir and nelfinavir, as it is not recommended
- if you are taking a high dose of methotrexate, LOSEC MUPS may need to be temporarily

withdrawn.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

Side effects to consider which may affect ability: blurred vision, dizziness and confusion.

It is not always possible to predict to what extent LOSEC MUPS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LOSEC MUPS affects them.

LOSEC MUPS contains sugar spheres

LOSEC MUPS contains sugar spheres which may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LOSEC MUPS.

3. How to take LOSEC MUPS

Do not share medicines prescribed for you with any other person.

Always take LOSEC MUPS exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many tablets to take and when to take them. The strength of the tablets you take and the length of time you take them for will depend on what conditions you are suffering from. You can take your tablets with food or on an empty stomach. The tablets should not be chewed or crushed. LOSEC MUPS should be taken in the morning and the tablets should be swallowed whole, with half a glass of water.

If you have problems with swallowing tablets and for children who can drink or swallow semi-solid food:

Break the tablet and put it in a spoonful of non-carbonated water. If you wish you can then mix it with some fruit juice or applesauce. Drink immediately or within 30 minutes. Always stir just before drinking. Rinse it down with half a glass of water. DO NOT USE milk or carbonated water. The solid particles contain the medication. The pellets must not be chewed or crushed.

Recommended dosage:

Duodenal ulcer, gastric ulcer and reflux oesophagitis:

Depending on the severity, the dose is 20 – 40 mg once daily for 2 – 8 weeks.

To prevent a duodenal ulcer from returning and when patients with healed reflux oesophagitis are being treated for a long time, the recommended dose is 10 mg once daily. If needed the dose can be increased to 20 – 40 mg once daily.

To prevent a gastric ulcer from returning, the recommended dose is 20 – 40 mg once daily.

Symptomatic gastro-oesophageal reflux disease:

The recommended dosage is 20 mg daily for 4 weeks. Patients may respond adequately to 10 mg daily, and therefore individual dose adjustment should be considered.

Functional dyspepsia:

For the relief of symptoms in patients with epigastric pain/discomfort with or without heartburn, the recommended dosage is 20 mg once daily for 4 weeks.

NSAID associated gastroduodenal lesions:

The recommended dosage of LOSEC MUPS is 20 mg once daily. Symptom resolution is rapid, and in most patients, healing occurs within 4 weeks. For those patients who may not be fully healed after the

initial course, healing usually occurs during a further 4 weeks treatment period.

For the prevention of NSAID associated gastric ulcers, duodenal ulcers, gastroduodenal erosions and dyspeptic symptoms, the recommended dosage of LOSEC MUPS is 20 mg once daily.

Helicobacter pylori positive duodenal ulcers:

The recommended dosage of LOSEC MUPS is 40 mg once daily or 20 mg twice a day combined with certain prescribed antibiotics.

Zollinger-Ellison Syndrome:

The recommended initial dosage is 60 mg once daily. Your doctor will adjust the dosage according to your needs and also decide for how long you should take the medicine. With doses above 80 mg daily, the dose should be divided and given twice daily.

Children:

Severe ulcerative reflux oesophagitis in children from 1 year and older:

The recommended dosage regime is:

<i>Weight:</i>	<i>Dosage:</i>
10 – 20 kg	LOSEC MUPS: 10 mg once daily
> 20 kg	LOSEC MUPS: 20 mg once daily

If needed, dosage may be increased to 20 mg and 40 mg respectively.

Elderly:

No dose adjustment is necessary in the elderly.

Impaired renal function:

No dose adjustment is required in patients with impaired renal function.

Impaired liver function:

Patients with severe liver disease rarely need more than 10 – 20 mg per day.

If you have the impression that the effects of LOSEC MUPS are too strong or too weak, talk to your doctor or pharmacist, who may wish to change your treatment.

If you take more LOSEC MUPS than you should

If you take more tablets than your normal dose, contact your doctor or nearest hospital immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LOSEC MUPS

Take the last missed dose as soon as you remember, then go back to your regular schedule. However, if it is almost time for your next dose, do not take the missed tablet; just take your next dose on time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LOSEC MUPS can have side effects.

Not all side effects reported for LOSEC MUPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOSEC MUPS, please consult your healthcare provider for advice.

If any of the following side effects happen, stop taking LOSEC MUPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing (severe allergic reaction).

- Rash or itching (severe skin reactions).
- Fainting, decreased consciousness.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to LOSEC MUPS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Discomfort/tightness in the chest.
- Signs of recurrent infections such as fever or sore throat.
- A decrease in the amount of urine, blood in the urine, tiredness, nausea and lack of appetite which can be symptoms of kidney problems. Sometimes fever, rash, joint pains may be present.
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common / Frequent side effects:

- headache
- diarrhoea
- constipation
- stomach ache
- nausea/vomiting
- wind
- masses of cells on the lining inside your stomach, known as fundic gland polyps.

Uncommon / Less frequent side effects:

- skin rash
- dermatitis

- itchy skin
- sensation of burning/ prickling/ numbness
- dizziness, light-headedness
- difficulty sleeping
- feeling sleepy
- sensation of movement of oneself or of one's surroundings
- feeling ill
- inflammation in the gut (leading to diarrhoea)
- sore joints and muscles
- muscular weakness
- hair loss
- dry mouth
- inflammation in the mouth
- gastrointestinal fungal infection
- disorientation, aggression, confusion
- blood disorders
- development of breasts in males
- taste disorders
- low blood sodium and low blood magnesium (which may result in low blood calcium and/or blood potassium)
- if you are very ill, you may feel confused, nervous, depressed or hallucinate
- sensitivity to sunlight
- increased sweating
- blurred vision
- fracture of hip, wrist or spine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (MedSafety X SAHPRA) and eReporting platform (who-umc-org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of LOSEC MUPS.

5. How to store LOSEC MUPS

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep your tablets in the container they came in and keep the container tightly closed. Replace cap firmly after use.

Do not use after the expiry date stated on the container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOSEC MUPS contains

- The active substance is omeprazole.

Each Losec MUPS 10 tablet contains: Omeprazole magnesium equivalent to omeprazole 10 mg

Each Losec MUPS 20 tablet contains: Omeprazole magnesium equivalent to omeprazole 20 mg

Each Losec MUPS 40 tablet contains: Omeprazole magnesium equivalent to omeprazole 40 mg

- The other ingredients are:

Glycerol monostearate 40-55, hydroxypropylcellulose (E463), hydroxypropyl-methylcellulose (E464), iron oxide reddish brown CI 77491 (E172) (10 mg, 20 mg, 40 mg tablets), iron oxide yellow CI 77492 (E172) (10 mg tablets), magnesium stearate, methacrylic acid copolymer type C, microcrystalline cellulose, paraffin synthetic, polyethylene glycol 6000, polysorbate 80 (E434), polyvinylpyrrolidone crosslinked (E1202), sodium hydroxide, (E524), sodium stearyl fumarate, sugar spheres 0,250 – 0,355, talc, titanium dioxide CI 77891 (E171), triethyl citrate (E1505).

What LOSEC MUPS looks like and contents of the pack

LOSEC MUPS 10: Light-pink, oblong, biconvex, film-coated tablet engraved with  on one side and 10 mg on the other side.

LOSEC MUPS 20: Pink, oblong, biconvex, film-coated tablet engraved with  on one side and 20 mg on the other side.

LOSEC MUPS 40: Red-brown, oblong, biconvex, film-coated tablet engraved with  on one side and 40 mg and a score on the other side.

LOSEC MUPS are stored in plastic containers of 7, 14, 28 and 30 tablets.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

An electronic copy of the Professional Information (PI) is available on the Equity website

<http://www.equitypharmaceuticals.co.za> or <http://www.sahpra.org.za>.