

PROPOSED PATIENT INFORMATION LEAFLET

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 or your pharmacist.
- LOSEC MUPS been prescribed for you personally and you should not share your LOSEC MUPS with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS:

S4

NAME OF MEDICINAL PRODUCT (and dosage form):

Losec MUPS® 10; Losec MUPS® 20; Losec MUPS® 40 (Tablet)

The active substance is omeprazole.

1. WHAT LOSEC MUPS CONTAINS:

LOSEC MUPS 10: Each tablet contains omeprazole 10 mg

LOSEC MUPS 20: Each tablet contains omeprazole 20 mg

LOSEC MUPS 40: Each tablet contains omeprazole 40 mg

The other inactive ingredients are:

Glycerol monostearate, hydroxypropyl methylcellulose, hydroxypropylcellulose, iron oxide (E 172), macrogol (polyethylene glycol), magnesium stearate, methacrylic acid co-polymer, microcrystalline cellulose, paraffin, polysorbate, polyvinylpyrrolidone crosslinked, triethyl citrate, sodium stearyl fumarate, sugar spheres, talc, titanium dioxide (E 171).

2. WHAT LOSEC MUPS ARE USED FOR:

LOSEC MUPS are 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:

- 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).

3. BEFORE YOU TAKE LOSEC MUPS:

Do not take LOSEC MUPS:

- if you are allergic to omeprazole
- if you are allergic to other “proton pump inhibitors” or any of the other ingredients of LOSEC MUPS.

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 are taking any of the following medicines used to prevent or treat:
 - fungal infections (itraconazole, ketoconazole, voriconazole)
 - anxiety (diazepam)
 - epilepsy (phenytoin)
 - intermittent claudication (cilostazol)
 - blood clotting (warfarin or other vitamin K blockers or clopidogrel)
- 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.

Some population studies have indicated that the use of proton pump inhibitors (like LOSEC MUPS) may be associated with a small increased risk of osteoporotic bone fractures (osteoporosis is a condition where certain bones become brittle). However, other similar population-based studies found no such increased risk. It has not been established that LOSEC MUPS causes fractures. Please inform your doctor if you have been diagnosed with osteoporosis (brittle bone disease).

Pregnancy and breastfeeding

You should not use LOSEC MUPS when pregnant or breastfeeding your baby.

If you are pregnant or breast feeding your baby while taking LOSEC MUPS, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

LOSEC MUPS is unlikely to affect your ability to drive or to operate machinery.

Taking other medicines with LOSEC MUPS:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of LOSEC MUPS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor or pharmacist:

- if you are taking any of the following medicines used to prevent or treat:
 - fungal infections (itraconazole, ketoconazole, voriconazole)
 - anxiety (diazepam)
 - epilepsy (phenytoin)
 - blood clotting (warfarin or other vitamin K blockers or clopidogrel)
 - intermittent claudication (cilostazol)
 - transplant rejection (tacrolimus)
 - heart problems (digoxin)
 - tuberculosis (rifampicin)
 - depression (St John's Wort/ hypericum perforatum)
- if you are using or 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.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

4. HOW TO TAKE LOSEC MUPS:

Always take LOSEC MUPS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell 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:

Weight: Dosage:

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, seek help at the nearest hospital or poison control centre.

If you forget to take LOSEC MUPS:

If you forget to take a dose, take it 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 dose, and just take the next dose on time. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

LOSEC MUPS can have side effects.

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

- sensitivity to sunlight
- severe skin reactions
- decreased consciousness
- swelling
- fever
- discomfort/tightness in the chest
- severe allergic reaction
- increased sweating
- blurred vision.

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 if you notice any of the following:

Frequent:

- headache
- diarrhoea
- constipation
- stomach ache
- nausea/vomiting
- wind.

Less frequent:

- skin rash
- dermatitis
- itchy skin

- sensation of burning/ prickling/ numbness
- dizziness
- difficulty sleeping
- feeling sleepy
- sensation of movement of one's self 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
- kidney and liver problems
- 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.

Not all side effects reported for LOSEC MUPS are included in this leaflet. Should your general health worsen while taking LOSEC MUPS, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF LOSEC MUPS:

Keep all medicines out of the reach and sight 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 LOSEC MUPS 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).


7. PRESENTATION OF LOSEC MUPS:

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

8. IDENTIFICATION OF LOSEC MUPS:

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.

9. REGISTRATION NUMBERS:

LOSEC MUPS 10: 32/11.4.3/0222

LOSEC MUPS 20: 32/11.4.3/0223

LOSEC MUPS 40: 32/11.4.3/0224

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

AstraZeneca Pharmaceuticals (Pty) Limited

Building 2, Northdowns Office Park,

17 Georgian Crescent West, Bryanston,
Johannesburg,
2021

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

To be allocated.

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