

# LOSEC MUPS TABLET

Omeprazole (10mg, 20mg)

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## What LOSEC MUPS is used for

Losec MUPS is used to treat the following health conditions:

- Ulcers in the upper part of the intestine (Duodenal ulcer).
- Stomach ulcers (Gastric ulcer).
- Stomach ulcers or ulcers in the upper part of the intestine caused by your medicine for pain and inflammation (NSAID associated gastric and duodenal ulcers or erosions).
- Ulcers which are infected with bacteria called *Helicobacter pylori* (*Helicobacter pylori* eradication in peptic ulcer disease).
- Disease with symptoms caused by a return flow of fluid from the stomach (Symptomatic gastro-oesophageal reflux disease or reflux oesophagitis).
- Acid related upper abdominal pain or discomfort (Acid related indigestion).
- Hormone producing tumours in the pancreas causing excess acid in the stomach (Zollinger-Ellison syndrome).

## How LOSEC MUPS works

Losec MUPS is a type of medicine called a 'proton pump inhibitor'. It reduces the production of acid in your stomach.

## Before you use LOSEC MUPS

### - When you must not use it

Do not take Losec MUPS if you are allergic to omeprazole or similar medication or any of the other ingredients.

### - Before you start to use it

Inform your health care professional if,

- you have any alarming symptoms (e.g. significant unintentional weight loss, recurrent vomiting, difficulty swallowing, severe or persistent

diarrhoea, vomiting blood or blood in your stools)

- you are taking medicines for Human Immunodeficiency Virus (HIV), such as atazanavir or if you have reduced vitamin B12 (cyanocobalamin) absorption or body stores,
- you have hereditary problems of sugar intolerance such as fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency

Some population studies have indicated that the use of proton pump inhibitors (like Losec MUPS) may be associated with a small increased risk for 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.

Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections

If you are undergoing long-term treatments, especially when exceeding a treatment period of 1 year, the doctor may arrange regular appointments for you.

### Pregnancy

Tell your doctor if you are pregnant or trying to become pregnant. Losec MUPS can be used in pregnancy. If you are pregnant, only take Losec MUPS on the advice of your doctor.

### Breast-feeding

Tell your doctor if you are breast-feeding. Losec MUPS may be used during breastfeeding. If you are breastfeeding, only take Losec MUPS on the advice of your doctor.

### - Taking other medicines

Medicine effects may be influenced if Losec MUPS is taken at the same time as some medicines used to treat fungal infections (itraconazole, ketoconazole, voriconazole), anxiety (diazepam), epilepsy (phenytoin), prevent blood clotting (warfarin or other vitamin K

blockers or clopidogrel), treat blood circulation disorder (cilostazol), prevent transplant rejection (tacrolimus), treat heart problems (digoxin), and also if you are having treatment for tuberculosis (rifampicin), St John's Wort (hypericum perforatum) (used to treat depression), or a certain type of cancer medication (such as erlotinib) and certain antibiotics (such as Clarithromycin).

Taking omeprazole at the same time as some medicines for Human Immunodeficiency Virus (HIV), such as atazanavir and nelfinavir, is not recommended.

If you are taking a high-dose of methotrexate (a chemotherapy medicine used to treat cancer), omeprazole 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.

## How to use LOSEC MUPS

### - How much to use

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.

You can take your tablets with food or on an empty stomach. The tablets should not be chewed or crushed. They should be swallowed whole, with half a glass of water. This is because the tablets contain coated pellets which stop the medicine from being broken down by the acid in your stomach.

If you have problems with swallowing tablets, break the tablet and mix it with some water or fruit juice. You can drink immediately or within 30 minutes. Always stir just before drinking. Rinse it down with half a glass of water.

### - When to use it

Duodenal ulcer, Gastric ulcer, Reflux oesophagitis

Depending on the severity of the ulcer or

reflux oesophagitis, the recommended dose is 20-40mg taken once a day, for 2-8 weeks. To prevent a duodenal ulcer from coming back and people with healed reflux oesophagitis are being treated for a long time, the recommended dose is 10-40mg taken once a day. To prevent a gastric ulcer from coming back, the recommended dose is 20-40mg taken once a day.

Symptomatic gastro-oesophageal reflux disease.

The recommended dose is 10-20mg taken once a day for 4 weeks.

Acid related indigestion.

For relief of symptoms with abdominal pain or discomfort the recommended dose is 10-20mg once a day for 4 weeks.

NSAID associated gastric and duodenal ulcers or erosions.

To heal your ulcer caused by your medicine for the pain and inflammation, the recommended dose is 20mg taken once a day for 4-8 weeks. To prevent the ulcer or pain from coming back when you continue to take your medicine for the pain and inflammation the recommended dose is also 20mg once a day.

Helicobacter pylori eradication in peptic ulcer disease

*Losec MUPS tablets taken with two antibiotics.*

Losec MUPS 20mg with amoxicillin 1g and clarithromycin 500mg each twice daily for 1 week **or**

Losec MUPS 20mg with metronidazole 400mg (or tinidazole 500mg) and 250mg clarithromycin each twice daily for 1 week **or**

Losec MUPS 40mg once daily with amoxicillin 500mg and metronidazole 400mg both three times a day for 1 week.

*Losec MUPS tablets taken with one antibiotic.*

Losec MUPS 40-80mg daily with amoxicillin 1.5g (doses up to 3g) in divided doses a day for 2 weeks **or** Losec MUPS 40mg once daily with 500mg clarithromycin three times a day for 2 weeks. If your symptoms do not go

away after you have been given one of these treatments, your doctor may repeat the same treatment, or try one of the other treatments.

Zollinger-Ellison syndrome.

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

Elderly.

The dose does not need to be adjusted in the elderly.

People with impaired kidney or liver function

People with severe liver disease rarely need more than 10-20mg per day. The dose does not need to be adjusted in people with impaired kidney function. If you have the impression that the effect is too strong or too weak, talk to your doctor or pharmacist.

Children

Losec MUPS 10mg and 20mg are not recommended to be used in children

- How long to use it

The strength of tablet you take and the length of time you take them for will depend on what conditions you are suffering from.

- If you forget to use it

If you miss 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 tablet, just take your next dose on time. Do not take a double dose to make up for forgotten doses.

- If you use too much (overdose)

If you may have taken more than you should, talk to a doctor or pharmacist immediately. Although no symptoms have been observed in people who have taken very high doses of omeprazole, we advise you to call your doctor or pharmacist straight away in case of an overdose.

Nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache have been reported. Also apathy, depression and confusion have been described in single cases.

**While you are using it**

- Things you must do

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

- Things you must not do

Do not stop taking your dose without talking to your Healthcare provider.

- Things to be careful of

Driving and using machines: Losec MUPS is unlikely to affect your ability to drive or to operate machinery. If affected, do not drive or operate heavy machinery.

If you have severe liver problems, you should discuss this with your doctor, as he/she may wish to reduce the dose.

**Side effects**

Like all medicines, Losec MUPS can have side effects. The following undesirable effects have been reported: headache, diarrhoea, constipation, stomach ache, feel sick / be sick, and wind.

On uncommon occasions, there have been reports of: skin rash, skin inflammation, itchiness (hives), sensation of burning / prickling / numbness, dizziness, difficulty sleeping, feeling sleepy and sensation of movement of one's self or of one's surroundings, feeling ill.).

There have been a few isolated cases of: inflammation in the gut (leading to diarrhoea), sensitivity to sunlight, severe skin reactions, hair loss, sore joints and muscles, muscular weakness, dry mouth, inflammation in the mouth, gastrointestinal fungal infection, disorientation /aggression/ confusion/decreased consciousness (if you already have severe liver disease), 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 i.e., leukopenia, thrombocytopenia, agranulocytosis and pancytopenia), development of breasts in males, swelling, fever, discomfort / tightness in the chest, severe allergic reaction (anaphylactic reaction/ shock), increased sweating, blurred vision, taste disorders, low blood sodium and low blood magnesium (which may result in low blood calcium and/or low blood potassium). If you are very ill, you may feel confused, nervous, depressed or hallucinate.

If you suffer from any of these reactions, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Other undesirable effects may occur. If you have any bothersome or unusual reaction while taking Losec MUPS, check with your doctor or pharmacist right away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling TEL: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

### Storage and Disposal of LOSEC MUPS

#### Storage



- Keep out of the reach and sight of children
- Do not store above 25° C.
- Store in the original package
- Keep the container tightly closed
- Do not use Losec MUPS after the expiry date on the label

#### Disposal

- Remember to return any unused Losec MUPS to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### Product Description

#### - What it looks like

Losec MUPS come in two strengths, 10 and 20 mg of omeprazole magnesium.  
10 mg: Light-pink, oblong, biconvex, film-coated tablets, engraved with  on one side and 10 mg on the other side.  
20 mg: Pink, oblong, biconvex, film-coated tablets, engraved with  on one side and 20 mg on the other side.

Losec MUPS come in blister packs containing 14 tablets.

#### - Ingredients

Active ingredient:

The active substance is omeprazole magnesium.

Inactive ingredients:

The other ingredients are microcrystalline cellulose, glyceryl monostearate, hydroxypropyl cellulose, hypromellose, magnesium stearate, methacrylic acid copolymer type C, sugar spheres, white soft paraffin, macrogol 6000, polysorbate 80, crospovidone, sodium stearyl fumarate, talc, triethyl citrate, iron oxide, titanium dioxide, purified water.

#### - MAL numbers

10mg: MAL19992064AZ  
20mg: MAL19992065AZ

### Manufacturer

AstraZeneca AB  
15185 Södertälje, Sweden

### Product Registration Holder

AstraZeneca Sdn. Bhd.  
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1 Jalan PJU 7/3,  
Mutiar Damansara,  
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### Date of revision

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