

PACKAGE LEAFLET: INFORMATION FOR THE USER

Losec® Capsules 10 mg, 20 mg and 40 mg

omeprazole

Please read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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1. What Losec Capsules are and what they are used for

Losec Capsules contain a medicine called omeprazole. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Losec Capsules are used to treat the following conditions:

- 'Gastro-oesophageal reflux disease' (GORD).
- Acid indigestion which can cause stomach pain or discomfort (dyspepsia).
- Ulcers that are infected with bacteria called '*Helicobacter pylori*'. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers in the stomach or upper part of the gut (intestine). If you have had an ulcer in the past and need to keep taking a medicine called an NSAID (Non-Steroidal Anti-Inflammatory Drug), Losec Capsules can stop ulcers from forming or heal one that is already there.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).
- Prevention of damage to the lungs caused by breathing in fluids from the stomach. This can happen during an operation.

Further information about ulcers and GORD

If you have ulcers or gastro-oesophageal reflux disease (GORD), this section contains information about your condition.

What is an ulcer?

An ulcer is a break or hole in the lining of the stomach or the gut.

What causes an ulcer?

- Usually, there is a balance between the protection of the stomach or gut lining and the attack from stomach acid. Ulcers form when there is too much acid or not enough protection.
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) may occasionally cause ulcers. If you have had an ulcer in the past, but need to keep taking an NSAID, your doctor may prescribe Losec Capsules to protect your stomach or gut.
- A bacteria called '*Helicobacter pylori*' (H. pylori) can also cause ulcers. H. pylori lives in the protective lining of the gut. It is not known why some people are infected with it and others are not. If you have an ulcer that is infected with H. pylori, your doctor may prescribe antibiotics to treat the infection and allow the ulcer to heal.

What is gastro-oesophageal reflux disease (GORD)?

This is where acid from the stomach escapes into the food pipe (oesophagus). The food pipe does not have a protective lining. When acid gets into the food pipe, it can cause pain, inflammation and heartburn.

What should you do if you do not feel relief from your symptoms?

Talk to your doctor who will be able to review you and your treatment.

How can I help myself?

If you have **gastro-oesophageal reflux disease**, an **ulcer** or **acid indigestion**, as well as taking Losec Capsules, the following may help:

- Do not eat just before going to bed. Also, try raising the head of your bed by 20 cm.
- Lose weight if needed and do not wear tight clothing.
- Stop smoking.
- Eat less fat and more protein.
- Do not have caffeine, alcohol, tomatoes or hot spicy food - these can make your symptoms worse.

2. Before you take Losec Capsules

Do not take Losec Capsules if:

- You are allergic (hypersensitive) to omeprazole or any of the other ingredients of this medicine (listed in Section 6: Further information).
- You are taking a medicine called atazanavir (used to treat HIV).

Do not take Losec Capsules if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Losec Capsules.

Take special care with Losec Capsules

Check with your doctor or pharmacist before taking Losec Capsules if:

- You have any liver problems. This is because your doctor may reduce your dose.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription. This is because Losec Capsules can affect the way some medicines work and some medicines can have an effect on Losec Capsules.

Do not take Losec Capsules if you are taking the following medicine:

- Atazanavir (used to treat HIV).

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Losec Capsules.
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Losec Capsules.
- Digoxin (used for heart problems).
- Tacrolimus (used in organ transplants).

Pregnancy and breast-feeding

Before taking Losec Capsules, tell your doctor if you are pregnant, trying to get pregnant or breast-feeding. Your doctor will decide whether you can take Losec Capsules during this time.

Driving and using machines

Losec Capsules are not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Losec Capsules

Losec Capsules contain lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. How to take Losec Capsules

Always take Losec Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- You can take your capsules at any time of the day.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with a drink of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

What to do if you have trouble swallowing the capsules

If you or your child have trouble swallowing the capsules, you can do one of the following:

- Open your capsules and swallow the contents with half a glass of water.
- Or you can mix the contents into 2 teaspoons of still (non-fizzy) water.
 - Gently stir this mixture into a small amount of acidic fruit juice (such as apple, orange or pineapple) or into apple sauce or yogurt.
 - Then drink the mixture straight away or within 30 minutes. Always stir the mixture just before drinking it.
 - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine
 - do not chew or crush them.
- Or you or your child can suck the capsules. Then drink half a glass of water.

How much to take

- Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition, how old you are and how well your liver works.
- The usual doses are given below.

To treat heartburn caused by gastro-oesophageal reflux disease (GORD):

Adults:

- The usual dose is 20 mg once a day for 4 weeks. Your doctor may then tell you to continue taking the capsules or increase the dose. This will depend on how you respond to treatment.
- To stop your symptoms returning, your doctor may tell you to continue taking 20 mg or reduce the dose to 10 mg.

Children (1 year and older):

- The dose depends on the child's age and weight.
- The usual dose is 10 mg or 20 mg once a day for 2 to 8 weeks.
- If your child has trouble swallowing, see the section on 'What to do if you have trouble swallowing the capsules' above.

Please turn over ⇒

To relieve acid indigestion which causes stomach pain or discomfort (dyspepsia):

Adults:

- The usual dose is 10 mg or 20 mg once a day for 2 to 4 weeks.
- If you get no improvement in your symptoms, go back to your doctor.

To treat ulcers caused by *Helicobacter pylori* infection:

Adults:

- The usual dose is 40 mg once a day or 20 mg twice a day for 1 or 2 weeks.
- Your doctor will also tell you to take one or more of the following antibiotics: amoxicillin, clarithromycin, metronidazole (or tinidazole).
- Follow the directions for taking your medicine very carefully and if you are unsure about anything, ask your doctor.

Children (4 years and older):

- The dose depends on the child's weight.
- The usual dose is 10 mg or 20 mg twice a day for 1 week.
- Your child will also be given the following antibiotics to take at the same time as Losec Capsules: amoxicillin and clarithromycin.

To treat ulcers in the stomach or upper part of the gut (intestine):

Adults:

- The usual dose is 20 mg once a day for 4 to 8 weeks.
- The dose may be increased depending on how you respond to treatment.
- To stop an ulcer in your upper intestine from coming back, the usual dose is 10 mg once a day unless your symptoms return. If your symptoms return, your doctor may increase the dose.

To prevent and treat ulcers caused by NSAIDs (Non-Steroidal Anti-Inflammatory Drugs):

Adults:

- If you have had trouble with an ulcer in the past but need to keep taking an NSAID, the dose is 20 mg once a day.

To treat too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome):

Adults:

- The usual starting dose is 60 mg once a day.
- If the dose is more than 80 mg a day, take half the dose in the morning and half at night.

Before a hospital operation when you are going to be given a general anaesthetic:

Adults:

- The usual dose is 40 mg the evening before the operation, then another 40 mg 2 to 6 hours before the operation.

If you take more Losec Capsules than you should

If you take more Losec Capsules than prescribed by your doctor, talk to your doctor or pharmacist straight away.

If you forget to take Losec Capsules

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

4. Possible side effects

Like all medicines, Losec Capsules can cause side effects, although not everybody gets them. The side effects are usually mild and go away when you stop taking this medicine.

If you notice any of the following serious side effects, stop taking Losec Capsules and tell a doctor or contact the casualty department at your nearest hospital straight away:

- Swelling of the lips, tongue and throat, fever or wheezing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.

These effects are rare, affecting less than 1 in 1,000 people.

Other side effects include:

Common (affects less than 1 in 10 people)

- Headache.
- Effects on your stomach or gut: stomach pain, constipation, diarrhoea, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).

Uncommon (affects less than 1 in 100 people)

- Disturbed sleep (insomnia).
- Dizziness.
- Tingling feelings such as 'pins and needles'.
- Feeling sleepy.
- Spinning feeling (vertigo).
- Feeling light-headed or faint.
- Skin rash, lumpy rash (hives), itchy skin and dermatitis.
- Changes in blood tests that show how well your liver is working.
- Generally feeling unwell.

Rare (affects less than 1 in 1,000 people)

- Dry or sore mouth.
- An infection called 'thrush' which can affect the mouth or gullet and is caused by a fungus.
- Taste changes.
- Feeling anxious, confused or depressed.
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Skin rash on exposure to sunshine.
- Blurred vision.
- Hair loss (alopecia).
- Painful swollen joints.
- Aching muscles or muscle weakness.
- Increased sweating.
- Kidney problems.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Severe liver problems leading to liver failure and inflammation of the brain.
- Enlarged breasts in men.
- Being unable to get an erection (impotence).
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Blood problems such as reduced numbers of white cells or platelets. This can cause weakness, bruising or make infections more likely.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Losec Capsules

- Keep out of the reach and sight of children.
- Do not store above 30°C.
- Keep the capsules in the original container.
- Do not take your capsules after the expiry date shown on the carton. The expiry date refers to the last day of that month.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. Further information

What Losec Capsules contain

The active substance is omeprazole. Losec Capsules come in three strengths containing 10 mg, 20 mg or 40 mg of omeprazole.

The other ingredients are mannitol, hypromellose, cellulose microcrystalline, anhydrous lactose, sodium lauryl sulphate, disodium hydrogen phosphate dihydrate, hypromellose, methacrylic acid copolymer, macrogol, colours E171 and E172, gelatin and magnesium stearate.

What Losec Capsules look like and contents of the pack

- Losec Capsules 10 mg are pink.
- Losec Capsules 20 mg are pink/reddish-brown.
- Losec Capsules 40 mg are reddish-brown.
- Your medicine will come in a blister pack in cartons containing 7 or 28 capsules.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Losec Capsules 10 mg, 20 mg and 40 mg are held by AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, United Kingdom.

Losec Capsules 10 mg, 20 mg and 40 mg are manufactured by AstraZeneca AB, S-151 85, Södertälje, Sweden or AstraZeneca UK Ltd, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, United Kingdom.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference number
Losec Capsules 10 mg	17901/0132
Losec Capsules 20 mg	17901/0133
Losec Capsules 40 mg	17901/0134

This is a service provided by the Royal National Institute of Blind People.

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