

PACKAGE LEAFLET

Package leaflet: Information for the patient

Losec 40 mg powder and solvent for solution for injection

Omeprazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Losec is and what it is used for

Losec contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Losec powder and solvent for solution for injection can be used as an alternative to oral therapy.

2. What you need to know before Losec is given to you

You must not be given Losec:

- If you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6).
- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (used for HIV infection).

Do not use Losec if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before you are given this medicine.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before you are given Losec.

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with Losec treatment. Stop using Losec and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Losec may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you are given Losec or after you are given it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.

- You pass black stools (blood-stained faeces).
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea.
- You have severe liver problems.
- You have ever had a skin reaction after treatment with a medicine similar to Losec that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).

Taking a proton pump inhibitor like Losec, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

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. Remember to also mention any other ill-effects like pain in your joints.

When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age. There is limited experience with Losec for intravenous use in children.

Other medicines and Losec

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

You must not be given Losec if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

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

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Digoxin (used to treat heart problems)
- 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
- 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
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi))
- Erlotinib (used to treat cancer)
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Losec treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Losec to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Pregnancy, breast-feeding, and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take Losec if you are breast-feeding.

Driving and using machines

Losec is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Sodium content

Losec contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

3. How Losec is given to you

- Losec can be given to adults including the elderly.
- There is limited experience with Losec for intravenous use in children.

Being given Losec

- Losec will be given to you by a doctor who will decide how much you need.
- The medicine will be given to you as an injection into one of your veins.

If you are given more Losec than you should

If you think you have been given too much Losec, talk to your doctor straight away.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following rare (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people) but serious side effects, stop using Losec and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (severe allergic reaction). The frequency of this side effect is rare.
- 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'. The frequency of this side effect is very rare.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). The frequency of this side effect is rare.
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis). The frequency of this side effect is rare.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. The frequency of this side effect is rare.

Other side effects include:

Common side effects (may affect up to 1 in 10 people)

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

- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people)

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy.
- Spinning feeling (vertigo).
- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

Rare side effects (may affect up to 1 in 1,000 people)

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

Very rare side effects (may affect up to 1 in 10,000 people)

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Erythema multiforme.
- Muscle weakness.
- Enlarged breasts in men.

Not known (frequency cannot be estimated from the available data)

- Inflammation in the gut (leading to diarrhoea).
- If you are on Losec for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.
- Rash, possibly with pain in the joints.

Losec may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Losec

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store this medicine in the original package in order to protect from light.

Shelf life after reconstitution:

The reconstituted solution should not be stored at temperatures above 25°C and should be used within 4 hours after preparation. From a microbiological point of view, the product should be used immediately unless it has been reconstituted under controlled and validated aseptic conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Losec contains

- The active substance is omeprazole. Each vial of powder for solution for injection contains omeprazole sodium equivalent to 40 mg of omeprazole.
- The other ingredients are:
Powder for injection: Sodium hydroxide (for pH adjustment).
Solvent for injection: Citric acid monohydrate (for pH adjustment), macrogol 400, and water for injections.

What Losec looks like and contents of the pack

Losec 40 mg powder and solvent for solution for injection (Powder for injection; and Solvent for reconstitution of solution for injection) comes in a combination pack consisting of a vial containing dry substance (I) and an ampoule containing solvent (II).

The dry powder in the vial is made into a solution before it is given to you.

Pack sizes: 1x40 mg (I+II), 5x40 mg (I+II), 10x40 mg (I+II).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name of medicinal product
The Netherlands, Sweden	Losec

This leaflet was last revised in 2023-05-17

[To be completed nationally]

Other sources of information

Detailed information on this medicine is available on the web site of {MA/Agency}

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The following information is intended for medical or healthcare professionals only:

Losec solution for injection is obtained by dissolving the freeze-dried substance in the accompanying solvent. No other solvent should be used.

The stability of omeprazole is influenced by the pH of the solution for injection, which is why no other solvents or quantities should be used for dilution. Improperly prepared solutions can be identified by their yellow to brown discolouration and must not be used. Use only clear, colourless or pale yellowish-brown solutions.

Preparation

NOTE: Steps 1 to 5 must be performed in immediate sequence:

1. With a syringe draw all of the solvent from the ampoule (10 ml).
2. Add approximately 5 ml of the solvent to the vial with freeze-dried omeprazole.
3. Withdraw as much air as possible from the vial back into the syringe. This will make it easier to add the remaining solvent.
4. Add the remaining solvent into the vial, make sure the syringe is empty.
5. Rotate and shake the vial to ensure all the freeze-dried omeprazole has dissolved.

Losec solution for injection must be given only as an intravenous injection and it must not be added to infusion solutions. After reconstitution the injection should be given slowly over a period of at least 2.5 minutes at a maximum rate of 4 ml per minute.