

Losec®

Omeprazole 10 mg, 20 mg and 40 mg capsules.

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Losec**. It does not contain all the information that is known about **Losec**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Losec** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Losec is used for

Reflux Oesophagitis

Losec is used to treat the symptoms of reflux oesophagitis or reflux disease in adults and in children. This can be caused by "washing back" (reflux) of food and acid from the stomach into the gullet (oesophagus).

Reflux can cause a burning sensation in the chest rising up to the throat, also known as heartburn.

Losec is also used to help stop reflux oesophagitis coming back or relapsing.

Acid-Related Dyspepsia

Losec is used to treat acid-related dyspepsia.

Dyspepsia describes any regular upper abdominal pain or discomfort that is often, but not always, related to eating.

Peptic Ulcers

Losec is used to treat peptic ulcers. Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out from the stomach.

These ulcers can be caused by too much acid being made in the stomach.

Losec is also used to help stop gastric or duodenal ulcers coming back.

Peptic Ulcers Associated with *Helicobacter pylori* Infection

Most people who have a peptic ulcer also have a bacteria called *Helicobacter pylori* in their stomach. When

Losec is taken with antibiotics, they will kill *Helicobacter pylori* and let your peptic ulcer heal. When **Losec** is taken together with two antibiotics, they are more effective than taken one or two at a time. It is possible that the antibiotics may not always kill *Helicobacter pylori*. You may need further treatment.

Peptic Ulcers Associated with Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs. These medicines are commonly taken to treat joint disease or arthritis. **Losec** is also used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison Syndrome

Losec is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

How Losec works

Losec is a type of medicine called a proton-pump inhibitor.

Losec works by decreasing the amount of acid made by the stomach, to give relief of symptoms and allow healing to take place. This does not stop food being digested in the normal way.

Your doctor will have explained why you are being treated with **Losec** and told you what dose to take.

Follow carefully all directions given to you by your doctor. They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

There is no evidence that **Losec** is addictive.

Before you use Losec

If you plan to become pregnant, are pregnant or if you are breast feeding, you should always be very careful with the use of medicines.

You should tell your doctor if you become pregnant while using **Losec** or if you are prescribed **Losec** if you are breast feeding.

When you must not use it

Do not use Losec after the use by (expiry) date printed on the pack.

Do not use Losec if the packaging is torn or shows signs of tampering.

Do not use Losec to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Before you start to use Losec

You must tell your doctor if:

1. you have any allergies to

- any medicine containing a proton-pump inhibitor
- ingredients listed at the end of this leaflet
- any other medicines, foods, dyes or preservatives.

If you have an allergic reaction, you may get a skin rash, difficulty in breathing, hayfever, or feel faint.

2. you have any other medical conditions

Tell your doctor if you have been diagnosed with osteoporosis (brittle bone disease).

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- phenytoin
- warfarin
- diazepam
- ketoconazole
- itraconazole
- voriconazole
- cilostazol
- tacrolimus
- digoxin
- clopidogrel
- citalopram / escitalopram
- rifampicin
- atazanavir
- nelfinavir
- St John's Wort
- erlotinib or related medicines
- methotrexate
- other medicines that you buy at the chemist, supermarket or health food shop

These medicines may be affected by **Losec** or may affect how well it works.

Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

If you have not told your doctor about any of these things, tell them before you take any Losec.

How to use Losec

How much to take

Take one Losec capsule each day, unless your doctor has told you otherwise.

Adults

The dose of **Losec** is usually 20 mg a day, but may vary from 10 mg to 40 mg a day depending on what condition you are being treated for and how severe it is.

Children

The recommended dose in children with reflux oesophagitis is 10 mg once a day in children weighing 10-20 kg and 20 mg in children weighing more than 20 kg.

Swallow Losec capsules whole with a glass of water.

If you have trouble swallowing **Losec**, open the capsule over an empty glass or cup and swallow the content, or suspend the content in a slightly acidic fluid e.g. fruit juice, yoghurt or soured milk and take within 30 minutes. Or, suck the capsule until it opens (1-2 minutes) and swallow the content with liquid. Do not crush or chew the capsules. If the granules in the capsules are chewed or crushed they won't work properly.

Take Losec at about the same time each day, preferably in the morning. Keeping a regular time for taking **Losec** will help to remind you to take it.

In most patients, **Losec** relieves symptoms rapidly and healing is usually complete within 4 weeks.

Although **Losec** heals ulcers very successfully, it may not prevent them coming back at a later date. **Losec** can be taken to prevent these relapses.

If you are taking **Losec** with antibiotics, it is possible that the antibiotics may not kill *Helicobacter pylori*. You may need treatment with further antibiotics.

Tell your doctor if your symptoms return.

It does not matter whether you take Losec with food or on an empty stomach.

If you forget to take it

If you forget to take a dose, take it as soon as you remember, and then go back to taking it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

Overdose

Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident & Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Losec. Even if there are no signs of discomfort or poisoning.

While you are using Losec

You must use **Losec** exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Losec.

Tell your doctor if you become pregnant while you are taking Losec.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Losec.

Losec helps most people with stomach or duodenal ulcers or reflux disease, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- constipation
- nausea or vomiting
- diarrhoea and wind (flatulence)
- headache
- stomach pain

These are all mild side effects of **Losec**.

Some people may notice:

- skin rash, itchy skin
- muscle pain or weakness
- dizziness
- "pins and needles"
- changes in sleep patterns
- mood changes, confusion or depression
- increase in breast size (males)
- fever
- increased bruising
- dry or sore mouth
- blurred vision
- increased sweating
- hair loss
- tremor

Tell your doctor if you think you have any of these effects or notice anything else that is making you feel unwell.

Some people may get other side effects while taking **Losec**.

When taking **Losec**, 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 your doctor.

Other problems are more likely to arise from the ulcer itself rather than the treatment. For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion occurs during treatment with **Losec**
- you begin to vomit blood or food
- you pass black (blood-stained) motions.
- severe skin reaction which may include rash, itching, redness, blistering or peeling of the skin

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Losec**.

After using it

Storage

Keep your Losec capsules in the bottle with the lid firmly on until it is time to take them. If you take Losec out of the bottle it will not keep well. **Keep Losec in a cool, dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.** Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave it in the car on hot days.

Disposal

If your doctor tells you to stop taking Losec or the capsules have passed their expiry date, ask your pharmacist what to do with any capsules you have left over.

Product description

What Losec looks like

Losec 10 mg capsules are pink, marked 10 and A/OS in black ink.

Losec 20 mg capsules are pink and brown, marked 20 and A/OM in black ink.

Losec 40 mg capsules are reddish-brown, marked 40 and A/OL in black ink.

Ingredients

Each **Losec** capsule contains omeprazole 10, 20 or 40 mg as the active ingredient; plus, Mannitol (E421), hydroxypropyl cellulose, microcrystalline cellulose (E 460), lactose-anhydrous, sodium lauryl sulphate, sodium phosphate - dibasic_dehydrate, as enteric-coated granules in bottles of 30 capsules.

The enteric coating is hypromellose, macrogol 400 and methacrylic acid copolymer.

The gelatine (E441) capsule is coloured with red iron oxide (E 172) and titanium dioxide (E 171).

Losec does not contain gluten.

Marketed by:

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