LOSEC® and LOSEC® EXTRA

Omeprazole 10 mg and 20 mg gastro-resistant tablets

What is in this leaflet

This leaflet answers some common questions about Losec (including Losec Extra) tablets.

It does not contain all the information about Losec tablets. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. You should weigh the risks of taking Losec tablets against the benefits expected for you.

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

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

What Losec tablets are used for

Losec is presented in MUPS® tablets, built on patented technology. The MUPS tablets allow the active ingredient, omeprazole, to be contained within very small pellets (which form part of the tablet mix). These pellets have an enteric coating, allowing them to pass through the stomach without being broken down. The pellets release the active ingredient in the intestine, where it can be absorbed by your body and take effect. Without this enteric coating, the omeprazole would be destroyed by stomach acid and would not be effective.

Losec is used for the relief of reflux-like symptoms – heartburn or regurgitation. Heartburn is an acidic or burning feeling, rising up from the stomach towards the throat. The pain of heartburn, which is usually associated with acid regurgitation (reflux), can be caused or made worse by eating large meals, bending over or lying flat, and by hot, alcoholic or acidic drinks such as orange juice.

The symptoms below are not usually signs of acid reflux:

- cardiac-type chest pain – often felt as a pressure or squeezing in the chest with shortness of breath and pain that may extend into the shoulders, arms or up toward the back or neck.
- abdominal pain or discomfort
- nausea, belching or bloating
- sore throat or cough

See your pharmacist or doctor if you experience any of these symptoms.

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, giving relief from acid reflux symptoms. If you suffer from acid reflux more than once a week, Losec may be right for you. However, if you have reflux every day you should see your pharmacist or doctor.

Losec does not stop food being digested in the normal way.

Ask your pharmacist or doctor if you have any questions about whether this medicine is suitable for you.

This medicine is available without a doctor’s prescription, only through your pharmacy.

Before you use Losec

When you must not use it

Do not use Losec if you have an allergy to any medicine containing omeprazole, pantoprazole or lansoprazole, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include swelling of parts of the body, difficulty breathing, rash, itching or hives on the skin.

Do not use Losec after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your pharmacist or doctor.

Before you start to use Losec

See your pharmacist or doctor if you:

- are under 18 years of age
- are over 55 years of age and have not experienced reflux-like symptoms before, or the symptoms have changed recently
- have liver disease or liver problems
- are at risk of bleeding problems
- find swallowing is difficult or painful
- experience choking during the night
- have persistent regurgitation of food
- have vomited bright red blood, or vomit regularly
- have bowel movements that are black and/or tar-like, a symptom of gastrointestinal bleeding
- have unexplained or unintentional weight loss
- have, or have previously had, a stomach or duodenal ulcer
- you have, or are at risk of having, osteoporosis or osteoporotic fractures

If you have not told your pharmacist or doctor about any of the above, do so before you start using Losec.

See your pharmacist or doctor if you are pregnant or breastfeeding.

If you are pregnant or breast feeding, you should be careful using any medicine. Before using Losec you should get your pharmacist or doctor’s advice.
Taking other medicines
Tell your pharmacist or doctor if you are taking any other medicines, including any you have bought without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Losec may interfere with each other. These include

- clopidogrel (Plavix®) – a heart medication. Taking this medication with Losec is not recommended.
- citalopram/escitalopram – medicines used to treat depression
- clozapine – an antipsychotic medicine
- phenytoin (Dilantin®), carbamazepine – medicines used to treat epilepsy
- warfarin (Coumadin®, Marevan®) – a medicine to treat or prevent blood clots
- diazepam – a medicine for anxiety or tension
- ketoconazole,itraconazole and voriconazole – antifungal medicines
- clarithromycin, rifampicin – antibiotic medicines
- digoxin (Lanoxin®) – a medicine used for heart disease
- tacrolimus (Prograf®)
- antiretroviral medicines (AIDS medications) such as atazanavir, neflinavir and saquinavir
- erlotinib (Tarceva®) and methotrexate – anticancer medicines
- St. John’s wort – a herb included in some Dietary Supplements

These medicines may be affected by Losec or may affect how well it works. **Your doctor or pharmacist can advise you if you are taking any of these medicines.**

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

How to Use Losec

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

If you do not understand the instructions below, or on the carton, ask your pharmacist or doctor for help.

**How much to take**

**Losec 10 mg Tablets**

Initially take 2 tablets once daily (corresponding to 20 mg omeprazole). Take both tablets at the same time. When your symptoms improve reduce the dose to 1 tablet a day (corresponding to 10 mg omeprazole).

If your symptoms return, the dose may be increased to two 10 mg tablets (20 mg omeprazole) each day.

**Losec Extra 20 mg Tablets**

Take one tablet (corresponding to 20 mg omeprazole) once a day. Do not use Losec Extra for more than 14 days except on medical advice.
Use the lowest dose that controls your symptoms.

**Losec** does not work immediately. While you should get some symptom relief from the first day of taking **Losec**, it can take longer for **Losec** to become fully effective. If you need immediate relief an antacid may be taken in addition to **Losec**.

Do not exceed the recommended dose.

Take **Losec** or **Losec Extra** for 14 continuous days to get the best results. Two weeks of treatment may keep you free of heartburn or regurgitation for up to 3 months.

Prolonged use of **Losec** is not recommended, except on medical advice.

**How to take it**

**Swallow Losec tablets whole with half a glass of water.**

If you have trouble swallowing **Losec**, the tablets (which contain small pellets) can be dispersed in half a glass of non-carbonated water or fruit juice. Do not use carbonated drinks or milk. Stir until the tablets disintegrate and drink the liquid with the pellets – preferably immediately, or at least within 30 minutes. Rinse the glass with fluid and drink to ensure you get all the pellets.

Do not crush or chew the tablets, or the pellets contained within the tablets. If the pellets are chewed or crushed they won't work properly.

**When to take it**

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.

**Losec** should be taken prior to a meal.

**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.

**If you take too much (overdose)**

Telephone your doctor or the National Poisons and Hazardous Chemicals Information Centre Ph: 0800 POISON (0800 764 766) or go to the nearest Accident & Emergency department immediately if you think that you or anyone else may have taken too much **Losec**. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.
While you are using Losec

**Things you must do**
You must use Losec exactly as instructed on the pack or in this leaflet, or as your pharmacist or doctor has prescribed.

See your pharmacist or doctor if:

- your symptoms have not improved within 14 days of starting Losec
- your symptoms become worse while you are taking Losec
- you experience fever, nausea, a generally unwell feeling, tiredness, blood in the urine or weight loss. These are symptoms of interstitial nephritis, a rare side effect of omeprazole.
- you experience abnormal eye movements, fatigue, muscle spasms, cramps or weakness, numbness or convulsions. These can be symptoms of hypomagnesaemia, a possible side effect of taking omeprazole. Stop taking Losec and see your doctor or Accident and Emergency clinic right away.

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

**Things you must not do**
While you are taking Losec, do not take other acid-suppressing medicines such as ranitidine or cimetidine (H2-antagonists).

**Things to be careful of**
Be careful driving or operating machinery until you know how Losec affects you.

Losec very occasionally causes drowsiness or affects the vision of some people. Make sure you know how you react to Losec before you drive a car, operate machinery, or do anything else that could be dangerous.

**Things that may help to resolve heartburn or acid reflux**
Some self help measures suggested below may help your condition. Your pharmacist or doctor can give you more information about these measures.

**Dietary Modification**
Try to avoid:

- foods that aggravate your condition such as fatty and spicy foods, caffeine, tomatoes and orange juice.
- large meals late in the day
- lying down after meals
- tight fitting clothing after meals
- excessive alcohol and acidic beverages e.g. red wine

*Raising the Bed Head or Using a Larger Pillow*
This may help your condition if you experience reflux-like symptoms at night, or the symptoms are in your throat.

*Weight Loss and/or Not Smoking*

May also help your condition.

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### Side effects

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

*Losec* helps most people 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.

**Do not be alarmed by the following list of side effects. You may not experience any of them.**

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

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

- constipation
- diarrhoea
- nausea and vomiting
- diarrhoea and wind (flatulence)
- headache

These are the more common side effects of *Losec*. They are usually mild.

**Tell your doctor if you notice any of the following:**

- skin rash
- muscle pain, spasm, cramping or weakness
- dizziness
- “pins and needles”
- changes in sleep patterns, restlessness
- mood changes or confusion
- increase in breast size (males)
- fever
- increased bruising
- abnormal eye movements
- numbness

These side effects are less common but can be serious and may need medical attention.

This is not a complete list of all possible side effects. Others may also occur in some people and there may be some side effects not yet known.
Tell your pharmacist or doctor if you notice anything that is making you feel unwell, even if it is not on this list.

Ask your pharmacist or doctor if you don't understand anything on this list.

After using Losec

Storage
Keep your tablets in the blister pack until it is time to take them.
If you take Losec out of the packaging it may not keep well.

Keep the tablets in a cool, dry place where the temperature stays below 25°C.

Do not store them or any other medicine in the bathroom or near a sink. Do not leave them on a window sill or in the car.
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.

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

Product description

What Losec looks like
Losec 10 mg tablets are light-pink, oblong, biconvex film-coated tablets, engraved with a or on one side and 10 mg on the other side. They are available in packs of 7 or 14 tablets.

Losec Extra 20 mg tablets are pink, oblong, biconvex film-coated tablets, engraved with a or on one side and 20 mg on the other side. They are available in packs of 14 or 28 tablets.

Ingredients
Each Losec tablet contains 10 mg omeprazole and each Losec Extra tablet contains 20 mg omeprazole (in the form of omeprazole magnesium 10.3 mg and 20.6 mg respectively) as the active ingredient.

Losec tablets also contain:
- microcrystalline cellulose, glyceryl monostearate, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, methacrylic acid co-polymer, sugar spheres, paraffin, polyethylene glycol, polysorbate, polyvinylpyrrolidone crosslinked, sodium stearyl fumarate, talc, triethyl citrate, iron oxide, titanium dioxide

Losec tablets do not contain gluten or lactose.
Marketed by
Bayer New Zealand Limited
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This leaflet was prepared on 8 May 2015.

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Ref. Losec and Losec Extra Data Sheet dated 26 March 2015.