

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using LOSEC®?

LOSEC® contains the active ingredient omeprazole (as magnesium). LOSEC® is used to treat: the symptoms of reflux oesophagitis or reflux disease; peptic ulcers; peptic ulcers associated with helicobacter pylori infection; peptic ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs); and a rare condition called Zollinger-Ellison syndrome.

For more information, see Section [1. Why am I using LOSEC®?](#) in the full CMI.

2. What should I know before I use LOSEC®?

Do not use if you have ever had an allergic reaction to omeprazole magnesium or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use LOSEC®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LOSEC® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use LOSEC®?

- Take one LOSEC® tablet each day, unless your doctor has told you otherwise.
- Swallow LOSEC® whole with a glass of water. Do not crush or chew the tablets.
- If you have difficulty swallowing the tablets, follow the instructions in Section [4. How do I use LOSEC®?](#)

More instructions can be found in Section [4. How do I use LOSEC®?](#) in the full CMI.

5. What should I know while using LOSEC®?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using LOSEC®. • Tell your doctor if you become pregnant while you are taking LOSEC®. • Tell your doctor if your symptoms return.
Things you should not do	• Do not take LOSEC® to treat any other complaints unless your doctor tells you to. • Do not stop taking your medicine or change the dosage without checking with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how LOSEC® affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep it in a cool, dry place where the temperature stays below 25°C. • Keep your LOSEC® in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using LOSEC®?](#) in the full CMI.

6. Are there any side effects?

Mild side effects include: constipation, nausea or vomiting, diarrhoea, wind, stomach pain, headache, dizziness, skin rash, itchy skin, dry or sore mouth. Serious side effects (Call your doctor straight away, or go straight to the Emergency Department) include: swelling of the face, lips, mouth, tongue or throat, shortness of breath or difficulty in breathing, skin reaction (which may include rash, itching, redness, blistering or peeling of the skin) especially in sun-exposed areas with joint pain, ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals, blood in the urine, swelling of hands, feet or ankles, yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using LOSEC®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LOSEC®.**

Where to find information in this leaflet:

- [1. Why am I using LOSEC®?](#)
- [2. What should I know before I use LOSEC®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use LOSEC®?](#)
- [5. What should I know while using LOSEC®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using LOSEC®?

LOSEC® contains the active ingredient omeprazole (as magnesium). LOSEC® is a type of medicine called a proton-pump inhibitor. It 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.

Reflux Oesophagitis

LOSEC® is used to treat the symptoms of reflux oesophagitis or reflux disease.

This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus).

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

LOSEC® is also taken to help stop reflux oesophagitis coming back or relapsing.

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

LOSEC® is used to treat peptic ulcers associated with *helicobacter pylori* infection.

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

When LOSEC® is taken with antibiotics, they work to kill the bacterium and let your ulcer heal. You may need further treatment with antibiotics.

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

LOSEC® is used to treat peptic ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs).

Some peptic ulcers are caused by taking medicines called non-steroidal anti-inflammatory drugs (NSAIDs), a type of medicine used to treat pain or inflammation.

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.

This syndrome is where the stomach produces large amounts of acid, much more than in ulcers or reflux disease.

There is no evidence that LOSEC® is addictive.

2. What should I know before I use LOSEC®?

Warnings

Do not take LOSEC® if:

- you are allergic to omeprazole, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicine containing a proton pump inhibitor.
- Always check the ingredients to make sure you can use this medicine.
Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- you are also taking cilostazol.
Please check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by LOSEC®.
- 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.

Check with your doctor if you have:

- allergies to any other medicines, foods, dyes or preservatives.
- take any medicines for any other condition.
- any problems with your liver.
- any other medical conditions.
- been diagnosed with osteoporosis.
- ever had a skin reaction after treatment with a medicine similar to LOSEC® that reduces stomach acid.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Serious skin reactions including erythema multiforme (EM), Stevens Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) 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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take LOSEC® if you are pregnant or breastfeeding unless your doctor says so. Ask your doctor about the risks and benefits involved.

Check with your doctor if you are pregnant or intend to become pregnant.

It is not known if it is safe for you to take LOSEC® while you are pregnant. It may affect your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if your baby can take in LOSEC® from breast milk if you are breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Do not take LOSEC® if you are taking the following medicine:

- cilostazol - a medicine used to treat intermittent claudication.

Some medicines may interfere with LOSEC® and affect how it works.

- phenytoin - a medicine used to treat epilepsy or fits.
- warfarin and clopidogrel - medicines used to prevent blood clots.
- digoxin - a medicine used to treat heart conditions.
- diazepam - a medicine used to treat anxiety and some other conditions.
- St John's wort - a herbal remedy used to treat mood disorders.
- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection.
- clarithromycin or rifampicin - medicines used to treat infections.
- atazanavir and nelfinavir - medicines used to treat viral infections such as HIV.
- tacrolimus and mycophenolate mofetil - medicines used to assist in organ transplants.
- methotrexate - a medicine used to treat arthritis and some types of cancer.
- erlotinib or related medicines used to treat cancer.

These medicines may be affected by LOSEC® or may affect how well it works. You may need different amounts of

your medicine, or you may need to take different medicines. Your doctor 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 LOSEC®.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LOSEC®.

4. How do I use LOSEC®?

How much to take

- Take one LOSEC® tablet each day, unless your doctor has told you otherwise.
- Adults: The dose of LOSEC® is usually 20 mg a day. The dose 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 (1 year or older): The dose of LOSEC® is 10 mg a day for children 10 to 20 kg. This dose may be increased to 20 mg if required. For children more than 20 kg the dose is 20 mg a day. This dose may be increased to 40 mg if required.
- Follow the instructions provided and use LOSEC® until your doctor tells you to stop.

When to take LOSEC®

- Take LOSEC® at about the same time each day.
- Keeping a regular time for taking LOSEC® will help to remind you to take it.
- LOSEC® can be taken with food or on an empty stomach.

How to take LOSEC®

- Swallow LOSEC® whole with a glass of water. Do not crush or chew the tablets.
- If the tablets are chewed or crushed, they will not work properly.
- Keep taking LOSEC® for as long as your doctor recommends.
In most patients, LOSEC® relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking LOSEC® for as long as your doctor tells you to.

If you have difficulty swallowing the tablets:

1. Place the tablet in half a glass of non-carbonated water or fruit juice. Mineral water, carbonated fruit juices, or other liquids are not suitable.
2. Gently mix the tablet and liquid by stirring, taking care not to crush the tablet.
3. Stir until the tablet disperses into little pellets.
4. Drink the liquid with the pellets immediately, or within 30 minutes. Do not chew the pellets.
5. Rinse the glass with half a glass of water and drink.

If you forget to use LOSEC®

LOSEC® should be used regularly at the same time each day. If you miss your dose at the usual time, 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 you missed.

If you use too much LOSEC®

If you think that you have used too much LOSEC®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using LOSEC®?

Things you should do

Take LOSEC® exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking LOSEC®.

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®.

Tell your doctor if your symptoms return.

Although LOSEC® can heal ulcers successfully, it may not prevent them recurring at a later date.

If you need to have any medical tests while you are taking LOSEC®, tell your doctor.

It may affect the results of some tests.

Remind any doctor, dentist or pharmacist you visit that you are using LOSEC®.

Things you should not do

- Do not take LOSEC® to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or change the dosage without checking with your doctor.
If you stop taking it suddenly or change the dose, your condition may worsen, or you may have unwanted side effects.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how LOSEC® affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your LOSEC® in the blister pack until it is time to take them.
If you take LOSEC® out of the blister pack they will not keep well.
- Keep it in a cool, dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
These side effects are usually mild. • constipation • nausea or vomiting • diarrhoea • wind • stomach pain • headache • dizziness • skin rash, itchy skin • dry or sore mouth	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
These are serious side effects that may require medical attention. Serious side effects are rare. - muscle pain or weakness, joint pain "pins and needles" - changes in sleep patterns - mood changes, confusion or depression - blurred vision - increase in breast size (males) - fever - increased bruising - increased sweating - hair loss - tremor - pain or indigestion that occurs during treatment with LOSEC® - you begin to vomit blood or food - you pass black (blood-stained) motions treatment > 3 month possibly decrease magnesium blood levels resulting in fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate low magnesium blood levels may cause decrease of potassium or calcium levels in blood	Tell your doctor immediately if you notice any of these serious side effects.
Very Serious side effects	
These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare. - swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing - shortness of breath or difficulty in breathing - skin reaction which may include rash, itching, redness, blistering or peeling of the skin - ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals - Widespread rash, high body temperature and enlarged lymph nodes - blood in the urine - swelling of hands, feet or ankles	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite - skin reaction, especially in sun-exposed areas, with joint pain	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Occasionally, LOSEC® may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

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 the treating physician.

Other problems are more likely to arise from the ulcer itself rather than the treatment.

Tell your doctor if your reflux symptoms return after you stop taking LOSEC®.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LOSEC® contains

Active ingredient (main ingredient)	Omeprazole magnesium
Other ingredients (inactive ingredients)	Glyceryl monostearate Hyprolose Hypromellose Magnesium stearate Methacrylic acid copolymer Microcrystalline cellulose Synthetic paraffin Macrogol 6000 Polysorbate 80 Crospovidone

	Sodium stearyl fumarate Purified talc Titanium dioxide Triethyl citrate Sodium hydroxide Sugar spheres (maize starch and sucrose) Iron oxide red (CI77491) Iron oxide yellow (CI77492)
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Do not take this medicine if you are allergic to any of these ingredients.

LOSEC® tablets do not contain gluten.

What LOSEC® looks like

LOSEC® 10 mg tablets are light pink, oblong shaped, marked with 10 mg on one side and a logo on the other side.

LOSEC® 20 mg tablets are pink, oblong shaped, marked with 20 mg on one side and a logo on the other side.

Australian Registration Numbers:

LOSEC® 10 mg (blister pack) - AUST R 63414

LOSEC® 20 mg (blister pack) - AUST R 63416

Who distributes LOSEC®

Pharmaco (Australia) Ltd

Level 9, Tower A

Zenith Towers

821 Pacific Highway

Chatswood, NSW 2067

Australia

Phone: 1800 201 564

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