

Omeprazole Sandoz®

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 Omeprazole Sandoz?

Omeprazole Sandoz contains the active ingredient omeprazole (as magnesium). Omeprazole Sandoz 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 Omeprazole Sandoz?](#) in the full CMI.

2. What should I know before I use Omeprazole Sandoz?

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 Omeprazole Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Omeprazole Sandoz 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 Omeprazole Sandoz?

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

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

5. What should I know while using Omeprazole Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using Omeprazole Sandoz.• Tell your doctor if you become pregnant while you are taking Omeprazole Sandoz.• Tell your doctor if your symptoms return.
Things you should not do	<ul style="list-style-type: none">• Do not take Omeprazole Sandoz 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	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Omeprazole Sandoz affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in a cool, dry place where the temperature stays below 25°C.• Keep your Omeprazole Sandoz in the blister pack until it is time to take them

For more information, see Section [5. What should I know while using Omeprazole Sandoz?](#) 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.

Omeprazole Sandoz®

Active ingredient(s): *omeprazole magnesium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Omeprazole Sandoz. **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 Omeprazole Sandoz.**

Where to find information in this leaflet:

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

1. Why am I using Omeprazole Sandoz?

Omeprazole Sandoz contains the active ingredient **omeprazole (as magnesium)**. Omeprazole Sandoz 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

Omeprazole Sandoz 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 to the throat, also known as heartburn.

Omeprazole Sandoz is also taken to help stop reflux oesophagitis coming back or relapsing.

Peptic Ulcers

Omeprazole Sandoz 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 of the stomach.

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

Omeprazole Sandoz is also used to help stop gastric and duodenal ulcers from coming back.

Peptic Ulcers Associated with *Helicobacter pylori* Infection

Omeprazole Sandoz is used to treat peptic ulcers associated with *helicobacter pylori* infection.

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

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.

Omeprazole Sandoz is used to heal and prevent ulcers associated with NSAIDs.

Zollinger-Ellison syndrome

Omeprazole Sandoz 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 Omeprazole Sandoz is addictive.

2. What should I know before I use Omeprazole Sandoz?

Warnings

Do not use Omeprazole Sandoz 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 Omeprazole Sandoz.
- you are also taking nelfinavir
- 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 Omeprazole Sandoz 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 omeprazole treatment. Stop using Omeprazole Sandoz 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 Omeprazole Sandoz 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 Omeprazole Sandoz 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 Omeprazole Sandoz 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 Omeprazole Sandoz if you are taking the following medicine:

- cilostazol, a medicine used to treat intermittent claudication.

Some medicines and Omeprazole Sandoz may interfere with each other. These include:

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

These medicines may be affected by Omeprazole Sandoz or may affect how well it works. You may need to use 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 the above, tell them before you start taking Omeprazole Sandoz.

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

4. How do I use Omeprazole Sandoz?

How much to take

- Take one Omeprazole Sandoz tablet each day, unless your doctor has told you otherwise.
- **Adults:** The dose of Omeprazole Sandoz is usually 20 mg a day. The dose may vary from 10 mg to 40 mg a day depending on the condition you are being treated for and how severe it is.
- **Children (1 year or older):** The dose of Omeprazole Sandoz 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 Omeprazole Sandoz until your doctor tells you to stop.

When to take Omeprazole Sandoz

- Take your medicine at the same time each day.
- Keeping a regular time for taking Omeprazole Sandoz will help to remind you to take it.

How to take Omeprazole Sandoz

- Omeprazole Sandoz can be taken with food or on an empty stomach.
- Swallow Omeprazole Sandoz 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. If you need to break a 20 mg tablet, hold the tablet with both hands and snap along the break line.

How to long to take Omeprazole Sandoz

- Keep taking Omeprazole Sandoz for as long as your doctor recommends.
- In most patients, Omeprazole Sandoz relieves symptoms rapidly and healing is usually complete within 4 weeks. Continue taking Omeprazole Sandoz 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 Omeprazole Sandoz

Omeprazole Sandoz 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 take 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 are not sure what to do, ask your doctor or pharmacist.

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

If you use too much Omeprazole Sandoz

If you think that you have used too much Omeprazole Sandoz, 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 Omeprazole Sandoz?

Things you should do

Take Omeprazole Sandoz exactly as your doctor has prescribed.

Tell your doctor if you become pregnant while you are taking Omeprazole Sandoz.

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

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking this medicine.

Tell your doctor if your symptoms return.

Although Omeprazole Sandoz 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 Omeprazole Sandoz, tell your doctor.

It may affect the results of some tests.

Remind any doctor, dentist, or pharmacist you visit that you are using Omeprazole Sandoz.

Things you should not do

- Do not take Omeprazole Sandoz to treat any other complaint unless your doctor tells you to.
- Do not give this medication 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 driving or operating machinery until you know how Omeprazole Sandoz affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your medicine in the original container. If you take it out of the container it may not keep well.
- Keep it in a cool, dry place where the temperature stays below 25°C. After opening of the bottle, store below 25°C and use within six months.
- Keep the container tightly closed.

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 window sills.

Keep it where young children cannot reach it.

When to discard your medicine

If your doctor tells you to stop taking Omeprazole Sandoz 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
Gastrointestinal or Gut related <ul style="list-style-type: none"> • constipation • diarrhoea • stomach pain • wind • nausea or vomiting 	Speak to your doctor if you have any of these less serious side

<p>Allergy related</p> <ul style="list-style-type: none"> • skin rash, itchy skin <p>Others</p> <ul style="list-style-type: none"> • headache • dry or sore mouth • dizziness 	<p>effects and they worry you.</p>
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<ul style="list-style-type: none"> • skin reaction which may include rash, itching, redness, blistering and peeling of the skin <p>Bleeding related</p> <ul style="list-style-type: none"> • blood in urine • ulcers, blisters or bleeding of the lips, eyes, mouth, nose, and genitals. <p>Liver related</p> <ul style="list-style-type: none"> • signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite. <p>Skin related</p> <ul style="list-style-type: none"> • skin reaction, especially in sun exposed areas, with joint pain • widespread rash, high body temperature and enlarged lymph nodes <p>Others</p> <ul style="list-style-type: none"> • swelling of hands, feet or ankles 	<p>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.</p>
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Serious side effects

Serious side effects	What to do
<p>Gastrointestinal or Gut related</p> <ul style="list-style-type: none"> • pain or indigestion that occurs during treatment with Omeprazole Sandoz. <p>Bleeding related</p> <ul style="list-style-type: none"> • you begin to vomit blood or food • you pass black (blood-stained) motions <p>Mood related</p> <ul style="list-style-type: none"> • changes in sleep patterns • depression, confusion, or mood changes <p>Eye related</p> <ul style="list-style-type: none"> • blurred vision <p>Musculoskeletal related</p> <ul style="list-style-type: none"> • muscle pain or weakness, joint pain • "pins and needles" <p>Others</p> <ul style="list-style-type: none"> • increase in breast size (males) • inability to get or maintain erection. • increased sweating • increased bruising • tremor • fever • hair loss • 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 	<p>Tell your doctor if you notice any of these serious side effects.</p>
<p>Very serious side effects</p>	<p>What to do</p>
<p>Allergy related</p> <ul style="list-style-type: none"> • swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing • shortness of breath or difficulty in breathing 	<p>You may need urgent medical attention or hospitalisation. These side effects are rare.</p>

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, Omeprazole Sandoz may be associated with changes in your liver or blood, which may require your doctor to do certain blood tests.

When taking Omeprazole Sandoz, 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 Omeprazole Sandoz.

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 Omeprazole Sandoz contains

Active ingredient (main ingredient)	omeprazole (as magnesium)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• copovidone• povidone• purified talc• titanium dioxide• methacrylic acid - ethyl acrylate copolymer (1:1)• glyceryl monostearate• propylene glycol• stearic acid• polysorbate 80• simethicone• microcrystalline cellulose• macrogol 6000• crospovidone• colloidal anhydrous silica• magnesium stearate• hypromellose• iron oxide red• sugar spheres (PI 2535)• sugar spheres/suglets 212/300 micrometres (50/70 Mesh) (PI 106902)
Allergens	sugars

Do not take this medicine if you are allergic to any of these ingredients.

What Omeprazole Sandoz looks like

Omeprazole Sandoz 20 mg enteric coated tablets - pink, oval, biconvex film-coated tablets with a breaking notch on both sides.

Available in blisters packs (AUST R 176179) and bottles (AUST R 176180) of 30 tablets.

Who distributes Omeprazole Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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