

Omeprazole Sandoz®

omeprazole (as magnesium) enteric-coated tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Omeprazole Sandoz. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you taking this medicine against the benefits it is expected to 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 OMEPRAZOLE SANDOZ IS USED FOR

The name of your medicine is Omeprazole Sandoz. It contains the active ingredient omeprazole (as magnesium).

Omeprazole Sandoz is used to treat the following conditions:

Reflux oesophagitis

This medicine is used to treat reflux oesophagitis (reflux disease) and to help stop it coming back or relapsing. Reflux can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe (oesophagus). Reflux can cause heartburn, a burning sensation in the chest rising up to the throat.

Treatment and prevention of peptic ulcers

Omeprazole Sandoz is used to help heal 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. This can be caused in part by too much acid being made in the stomach.

This medicine is also used to help stop gastric and duodenal ulcers from coming back.

Combination therapy for the treatment of peptic ulcers associated with *Helicobacter pylori* infection

Helicobacter pylori is a bacteria that often occurs in the stomach together with peptic ulcers. It is important to kill *Helicobacter pylori* to let your peptic ulcer heal. Omeprazole Sandoz is usually combined with two antibiotics to help kill this bacteria. However, it is possible that the antibiotics might not always be able to kill *Helicobacter pylori*.

Treatment and prevention of peptic ulcers associated with non-steroidal anti-inflammatory drugs (NSAIDs)

Non-steroidal anti-inflammatory drugs are used to relieve pain, swelling and other symptoms of inflammation, including arthritis and joint pain. Some peptic ulcers are caused by taking these NSAIDs.

Omeprazole Sandoz is used to treat and help prevent ulcers developing which are associated with long term NSAID use.

Zollinger-Ellison syndrome

Omeprazole Sandoz is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces very

large amounts of acid, much more than in ulcers and reflux disease.

Ask your doctor if you have any questions about why this medicine was prescribed for you.

Your doctor may have prescribed it for another reason.

How Omeprazole Sandoz works

Omeprazole Sandoz belongs to a group of medicines called proton pump inhibitors (PPIs).

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

There is no evidence that this medicine is addictive.

BEFORE YOU TAKE OMEPRAZOLE SANDOZ

When you must not take it

Do not take this medicine if:

- you are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description. Symptoms of an allergic reaction may include skin rash, fever, wheezing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.
- you are also taking cilostazol.
- you are also taking nelfinavir
- you are also taking medicines such as atazanavir or saquinavir that are used to treat viral infections such as HIV. Check with your doctor or pharmacist if you are taking these medicines. These medicines may be affected by Omeprazole Sandoz.
- you are taking any medicine containing a proton-pump inhibitor e.g. esomeprazole, lansoprazole and rabeprazole.
- you are pregnant or breastfeeding, unless permitted by your doctor. It is not yet known if it is safe for you to take this medicine while you are pregnant. It may affect your developing baby. It is also not yet known if this medicine passes into breast milk if you are breastfeeding. Ask your doctor about the risks and benefits involved in taking Omeprazole Sandoz while pregnant or breastfeeding.

Do not take this medicine after the 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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Also tell your doctor if you have or have had any problems with your liver or any other medical conditions.

Tell your doctor if you are taking other medicines that may cause low levels of magnesium in the blood

(hypomagnesaemia). For example diuretics.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking Omeprazole Sandoz.

Taking other medicines

Do not take Omeprazole Sandoz if you are taking the following medicine:

- cilostazol, a medicine used to treat intermittent claudication
- nelfinavir, a medicine used to treat viral infections such as HIV.

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

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

- clarithromycin (Klacid), or rifampicin (Rifadin), used to treat infections
- diazepam (Valium), used as a sedative or to treat anxiety
- ketoconazole (Nizoral), itraconazole (Sporanox) and voriconazole (Vfend), used to treat fungal infections
- phenytoin (Dilantin), used to treat epilepsy or fits
- warfarin (Coumadin, Marevan) and clopidogrel (Plavix), used to prevent blood clots
- atazanavir (Reyataz), used to treat viral infections such as HIV
- tacrolimus (Prograf), used as immunosuppressant, adjunct to liver or kidney transplantation
- St. John's Wort, used to treat anxiety, stress, nervous tension and some other conditions.
- 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 problems.

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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE OMEPRAZOLE SANDOZ

The dosage recommendation and duration of treatment will be determined for your specific condition by your doctor.

Follow your doctor's instructions about how and when to take Omeprazole Sandoz carefully.

They may differ from the information contained in this leaflet.

For adults, the usual dose is 20mg omeprazole per day. The dose may vary from 10mg to 40mg a day depending on the condition you are being treated for and how severe it is.

For children (one year or older), the dose depends on the body weight. For children 10kg to 20kg, the dose is 10mg omeprazole per day. This dose may be increased to 20mg if required. For children more than 20kg the dose is 20mg per day. This dose may be increased to 40mg if required.

Swallow the tablets with a glass of water.

If you need to break a 20 mg tablet, hold the tablet with both hands and snap along break line.

Take your medicine at the same time each day. It can be taken with or without food.

Symptoms will be relieved rapidly in most patients, and healing usually takes place within four weeks.

If your symptoms return, tell your doctor. If you have been treated for *Helicobacter pylori*, the antibiotics might not have killed the bacteria, and you will have to be treated again.

If you forget to take it

Take your dose as soon as you remember, and continue 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.

This may increase the chance of you getting an unwanted side effect.

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 take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Omeprazole Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, dizziness, abdominal pain, diarrhoea and headache.

WHILE YOU ARE TAKING OMEPRAZOLE SANDOZ

Things you must do

Always follow your doctor's instructions carefully.

Tell your doctor if you become pregnant while taking this medicine.

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.

Things you must not do

Do not stop taking this medicine without your doctor's permission.

Do not use this medicine to treat any other complaint unless your doctor says so.

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

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.

Things to be careful of

Be careful driving or operating machinery until you know how Omeprazole Sandoz affects you.

Things that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Aspirin and similar medicines used to treat arthritis, period pain or headaches** - these medicines may irritate the stomach and make your condition worse. Your doctor or pharmacist can suggest other medicines you can take.
- **Caffeine** - your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.
- **Eating habits** - eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down.
- **Weight** - if you are overweight, your doctor may suggest losing some weight to help your condition.

SIDE EFFECTS

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

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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
- diarrhoea
- abdominal pain
- flatulence (wind)
- headache
- nausea, vomiting

- dry or sore mouth
- dizziness
- skin rash, itchy skin.

These are the more common side effects of this medicine. Mostly, these are mild and short-lived.

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

- changes in sleep patterns
- blurred vision
- increased sweating
- hair loss
- dizziness
- frequent signs of infection such as fever, severe chills, sore throat or mouth ulcers
- increased bruising or bleeding more easily than normal
- increase in breast size (males)
- depression, agitation, confusion, mood changes or hallucinations
- muscle pain or weakness, joint pain
- sleepiness or drowsiness
- "pins and needles" (tingling or numbness) in the hands or feet
- tremor
- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite.
- Inability to get or maintain erection.
- Fractures, for example hip, wrist or spine.

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

These may be serious side effects of this medicine. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Omeprazole Sandoz and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the limbs, face, lips, mouth or throat which may cause difficulty in swallowing or breathing, itchy rash or hives. These are the symptoms of an allergic reaction.
- redness, blistering and peeling of the skin, accompanied by fever, chills and aching muscles
- blood in urine
- ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals.

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some health problems or complications may arise from the ulcer itself rather than the treatment.

For this reason, contact your doctor immediately if you notice any of the following:

- ongoing stomach pain or indigestion during treatment with this medicine
- passing black or blood-stained motions
- vomiting blood or food

- unexpected weight loss.

AFTER USING OMEPRAZOLE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine 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. Do not use after the printed expiry date. Keep the container tightly closed.

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

Heat and dampness can destroy some medicines.

Keep it where 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

Return any unused or out of date medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

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

Available in blisters packs and bottles of 30 enteric-coated tablets.

Ingredients

Active Ingredients:

Omeprazole Sandoz 20mg enteric-coated tablets - 20mg omeprazole (as magnesium)

Inactive ingredients:

- sucrose
- maize starch
- glucose
- 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.

This medicine does not contain lactose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
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20mg enteric-coated tablets: AUST R 176179 (blister packs)

20mg enteric-coated tablets: AUST R 176180 (bottles)