

OMEPRAZOLE SANDOZ IV

Omeprazole Powder for Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Omeprazole Sandoz IV. 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 risks of you using this medicine 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 Omeprazole Sandoz IV is used for

This medicine is used to treat and 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.

Ulcers can be caused in part by too much acid being made in the stomach.

This medicine is also used to help prevent gastric or duodenal ulcers from coming back.

Reflux oesophagitis

This medicine is used to treat and prevent reflux oesophagitis. This can be caused by "washing back"

(reflux) of food and acid from the stomach into the oesophagus (food pipe).

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

Zollinger-Ellison syndrome

This medicine 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 or reflux disease.

How Omeprazole Sandoz IV works

Omeprazole Sandoz IV belongs to a group of medicines called proton pump inhibitors. It works by decreasing the amount of acid made by the stomach. This does not stop food being digested in the normal way. It helps reduce the pain and also allows the ulcer to heal.

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

Your doctor may have prescribed it for another reason.

There is no evidence that this medicine is addictive.

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

Before you are given Omeprazole Sandoz IV

When you must not take it

Do not take this medicine if:

- 1. you have an allergy to:**

- omeprazole sodium
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

- 2. you are currently taking a medicine containing the active substance nelfinavir, used to treat HIV infections.**

Check with your doctor or pharmacist if you are taking any other medicines used to treat HIV infections, such as atazanavir.

- 3. 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 this medicine while pregnant or breastfeeding.

- 4. you are also taking cilostazol.**

Check with your doctor or pharmacist if you are taking cilostazol. This medicine will be affected by Omeprazole Sandoz IV.

Do not use this medicine after the expiry date printed on the pack has passed.

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

Before you are given it

You must tell your doctor if:

1. you have any allergies to:

- omeprazole sodium
- any medicine containing a proton-pump inhibitor
- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes.

2. you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using this medicine during pregnancy.

3. you are breastfeeding or intend to breastfeed.

This medicine is not recommended for use during breastfeeding.

4. you have or have had any problems with your liver or other medical conditions.

5. you are taking other medicines that may cause low levels of magnesium in the blood (hypomagnesaemia). For example diuretics.

If you have not told your doctor about any of the above, tell them before you are given Omeprazole Sandoz IV.

Taking other medicines

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

cilostazol, a medicine used to treat intermittent claudication.

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 IV may interfere with each other. These include:

- ketoconazole, itraconazole, voriconazole - medicines used to treat fungal infection

- diazepam - a medicine used to treat anxiety and some other conditions
- phenytoin - a medicine used to treat epilepsy or fits
- warfarin and clopidogrel - medicines used to prevent blood clots
- clarithromycin or rifampicin - medicines used to treat infections
- atazanavir and nelfinavir - medicines used to treat viral infection such as HIV
- erlotinib or related medicines used to treat cancer
- tacrolimus - used as immunosuppressant, adjunct to liver or kidney transplantation
- St. John's wort - a medicine used to treat anxiety, stress, nervous tension and some other conditions.
- digoxin - a medicine used to treat heart problems.

These medicines may be affected by Omeprazole Sandoz IV, or may affect how well it works. You may need different amounts of your medicine or you may need to use different medicines.

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

How Omeprazole Sandoz IV is given

Omeprazole Sandoz IV will be given to you in hospital by highly trained medical personnel.

It will be injected into a vein over a period of 20 to 30 minutes. This is called intravenous infusion.

Your doctor will decide what dose and how long you will receive this medicine.

In most patients, Omeprazole Sandoz IV relieves symptoms rapidly and it will be replaced with

omeprazole capsules as soon as you are well enough to swallow them.

Omeprazole Sandoz IV is usually given once daily and may be increased to twice daily depending on your response.

Ask your doctor if you want to know more about the dose of Omeprazole Sandoz IV you receive.

If you have been given too much (overdose)

As Omeprazole Sandoz IV will be given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being given this medicine, tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital.

You may need urgent medical attention.

Symptoms of an omeprazole overdose may include severe nausea (feeling sick) or vomiting, diarrhoea, confusion, headache, dizziness, abdominal pain and depression.

While you are being given Omeprazole Sandoz IV

Things you must do

Tell your doctor immediately if you become pregnant while being given this medicine.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given Omeprazole Sandoz IV.

Tell all doctors, dentists and pharmacists who are treating you that you are being given Omeprazole Sandoz IV.

Things to be careful of

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

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Omeprazole Sandoz IV.

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 of the side effects.

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

Ask your doctor, nurse 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
- nausea (feeling sick)
- vomiting
- headache
- abdominal pain
- excessive gas in stomach or bowel
- dry or sore mouth
- skin rash, itchy skin.

These side effects are usually mild.

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

- joint pain, muscle pain or weakness
- dizziness
- tingling or numbness in the hands or feet
- changes in sleep patterns & inability to sleep
- unusual hair loss or thinning of hair
- blurred vision or loss of vision
- increase in breast size (males)
- sleepiness or drowsiness

- agitation, confusion, mood changes or hallucinations
- depression or feeling of deep sadness & unworthiness
- bruising or bleeding more easily than normal
- increased sweating
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- 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.

These are serious side effects which may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

- swelling of 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
- blood in urine
- swelling of feet, hands and ankles.

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

Tell your doctor if you notice anything that is making you feel unwell.

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

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

Other health problems may arise from the condition being treated itself rather than the treatment.

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

- pain or indigestion during treatment with Omeprazole Sandoz IV
- vomiting blood or food
- passing black or blood-stained motions
- unexpected weight loss.

After being given Omeprazole Sandoz IV

Storage

Omeprazole Sandoz IV will be stored in the pharmacy or on the hospital ward. It will be stored in a cool dry place where the temperature stays below 25°C, protected from light.

Product description

What it looks like

Omeprazole Sandoz IV is a white to almost white powder. The powder is mixed with normal saline or 5% glucose before being injected. The reconstituted solution is a clear, colourless solution.

Ingredients

Active ingredient:

Each vial contains 42.56mg omeprazole sodium (this is equal to 40mg omeprazole).

Inactive Ingredients:

- disodium edetate
- sodium hydroxide.

Omeprazole Sandoz IV does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road,
Macquarie Park, NSW 2113
Australia
Tel: 1800 726 369

Novartis New Zealand Ltd
Private Bag 65904 Mairangi Bay
Auckland 0754
New Zealand
Tel: 0800 354 335

This leaflet was revised in
November 2017.

Australian Registration Number:

AUST R 127835