

# Omeprazole Sandoz® IV

## 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 being given Omeprazole Sandoz IV?

Omeprazole Sandoz IV contains the active ingredient omeprazole. Omeprazole Sandoz IV is used to treat and help heal peptic ulcers. This medicine is also used to help prevent gastric or duodenal ulcers from coming back.

For more information, see Section [1. Why am I being given Omeprazole Sandoz IV?](#) in the full CMI.

### 2. What should I know before I am given Omeprazole Sandoz IV?

Do not use if you have ever had an allergic reaction to omeprazole 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 am given Omeprazole Sandoz IV?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Omeprazole Sandoz IV 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 am I being given Omeprazole Sandoz IV?

- Omeprazole Sandoz IV will be given to you in hospital by highly trained medical personnel.
- Omeprazole Sandoz IV is usually given once daily and may be increased to twice daily depending on your response.

More instructions can be found in Section [4. How am I being given Omeprazole Sandoz IV?](#) in the full CMI.

### 5. What should I know while being given Omeprazole Sandoz IV?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are being given Omeprazole Sandoz IV.</li><li>• Tell your doctor immediately if you become pregnant while being given this medicine.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Omeprazole Sandoz IV affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Omeprazole Sandoz IV will be stored in the pharmacy or on the hospital ward.</li><li>• It will be stored in a cool dry place where the temperature stays below 25°C, protected from light.</li></ul>

For more information, see Section [5. What should I know while being given Omeprazole Sandoz IV?](#) in the full CMI.

### 6. Are there any side effects?

**Mild side effects** include: constipation, nausea or vomiting, diarrhoea, wind, stomach pain, headache, 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.

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® IV

Active ingredient(s): *Omeprazole*

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

## 1. Why am I being given Omeprazole Sandoz IV?

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

**Omeprazole Sandoz IV 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.

**Omeprazole Sandoz IV 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.

There is no evidence that this medicine is addictive

## 2. What should I know before I am given Omeprazole Sandoz IV?

### Warnings

**Do not use Omeprazole Sandoz IV if:**

- you are allergic to omeprazole sodium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- 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.
- 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 Omeprazole Sandoz IV if any of the above apply to you. If you are not sure, talk to your doctor, nurse or pharmacist before you are given this medicine.

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- have any allergies to:
  - any medicine containing a proton-pump inhibitor
  - any other substances, such as foods, preservatives or dyes.
- have or have had any problems with your liver or other medical conditions.
- are taking other medicines that may cause low levels of magnesium in the blood (hypomagnesaemia). For example diuretics

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?](#)

### Pregnancy and breastfeeding

Do not take Omeprazole Sandoz IV 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 IV while you are pregnant. It may affect your developing baby.

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

Omeprazole is excreted in breast milk but is not likely to influence the child when therapeutic doses are used.

### 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 IV if you are taking the following medicine:**

- cilostazol, a medicine used to treat intermittent claudication.

**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.

**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 IV.**

### 4. How am I being given Omeprazole Sandoz IV?

#### How much to use

- 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.

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

#### When am I being given Omeprazole Sandoz IV

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

#### If you have been given too much Omeprazole Sandoz IV

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.

If you experience severe side effects or think that you have used too much Omeprazole Sandoz IV, 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.

**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 being given Omeprazole Sandoz IV?

#### Things you should 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.

Remind any doctor, dentist or pharmacist you visit that you are being given Omeprazole Sandoz IV.

#### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Omeprazole Sandoz IV affects you.**

#### Drinking alcohol

**Tell your doctor if you drink alcohol.**

#### Looking after your medicine

- 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.

## 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
<b>Gut or Gastrointestinal related:</b> <ul style="list-style-type: none"><li>constipation</li><li>diarrhoea</li><li>nausea (feeling sick)</li><li>vomiting</li><li>abdominal pain</li><li>excessive gas in stomach or bowel</li><li>dry or sore mouth</li></ul> <b>General disorders:</b> <ul style="list-style-type: none"><li>headache</li></ul> <b>Skin related:</b> <ul style="list-style-type: none"><li>skin rash, itchy skin.</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>  <b>They are generally mild and do not cause patients to stop taking Omeprazole Sandoz IV.</b>

### Serious side effects

Serious side effects	What to do
<b>Muscle-Joint Related:</b> <ul style="list-style-type: none"><li>joint pain, muscle pain or weakness</li></ul> <b>General disorders:</b> <ul style="list-style-type: none"><li>dizziness</li></ul> <b>Mood and brain related:</b> <ul style="list-style-type: none"><li>changes in sleep patterns &amp; inability to sleep</li><li>sleepiness or drowsiness</li><li>agitation, confusion, mood changes or hallucinations</li><li>depression or feeling of deep sadness &amp; unworthiness</li></ul> <b>Eye related:</b> <ul style="list-style-type: none"><li>blurred vision or loss of vision</li></ul> <b>Bleeding related:</b> <ul style="list-style-type: none"><li>bruising or bleeding more easily than normal</li></ul>	<b>Tell your doctor as soon as possible if you experience any of the following symptoms.</b>

#### Liver related:

- signs of liver inflammation including yellowing of the skin or eyes, feeling generally unwell, nausea, vomiting, loss of appetite

#### Infection related:

- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers

#### Others:

- unusual hair loss or thinning of hair
- increase in breast size (males)
- increased sweating
- inability to get or maintain erection.
- fractures, for example hip, wrist or spine.

### Very serious side effects

Very serious side effects	What to do
<b>Allergy related:</b> <ul style="list-style-type: none"><li>swelling of face, lips, mouth, tongue or throat which may cause difficulty in breathing</li><li>shortness of breath or difficulty in breathing</li><li>skin reaction which may include rash, itching, redness, blistering or peeling of the skin</li></ul> <b>Skin related:</b> <ul style="list-style-type: none"><li>ulcers, blisters or bleeding of the lips, eyes, mouth, nose and genitals</li><li>widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)</li><li>a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis)</li></ul> <b>Heart related:</b> <ul style="list-style-type: none"><li>swelling of feet, hands and ankles.</li></ul> <b>Others:</b> <ul style="list-style-type: none"><li>blood in urine</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effect.</b>

**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.

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.

## 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](http://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 IV contains

<b>Active ingredient (main ingredient)</b>	omeprazole sodium
<b>Other ingredients (inactive ingredients)</b>	disodium edetate sodium hydroxide.

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

### What Omeprazole Sandoz IV looks like

Omeprazole Sandoz IV – 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 (Aust R 127835).

### Who distributes Omeprazole Sandoz IV

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

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