

PACKAGE INSERT: INFORMATION FOR THE USER

Omeprazole 40 mg Powder for solution for infusion
Omeprazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Omeprazole Infusion is and what it is used for
2. What you need to know before you are given Omeprazole Infusion
3. How Omeprazole Infusion is given to you
4. Possible side effects
5. How to store Omeprazole Infusion
6. Contents of the pack and other information

1. What Omeprazole Infusion is and what it is used for

Omeprazole Infusion contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Omeprazole Infusion can be used as an alternative to oral therapy.

2. What you need to know before you are given Omeprazole Infusion

You must not be given Omeprazole Infusion

- if you are allergic to omeprazole or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole)
- if you are taking a medicine containing nelfinavir (used for HIV infection).

You should not be given Omeprazole infusion 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.

Warnings and precautions

Omeprazole Infusion may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you are given Omeprazole Infusion, or after you are given it, talk to your doctor straight away.

- You lose a lot of weight for no reason and have problems swallowing
- You get stomach pain or indigestion
- You begin to vomit food or blood
- You pass black stools (blood-stained faeces)
- You experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea
- You have severe liver problems
- You are due to have a specific blood test (Chromogranin A)

- You have ever had a skin reaction after treatment with a medicine similar to Omeprazole that reduces stomach acid.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Omeprazole Infusion. Remember to also mention any other ill-effects like pain in your joints.

Taking a proton pump inhibitor like omeprazole, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

Children and adolescents

This medicine should not be given to children and adolescents under 18 years of age. There is limited experience with omeprazole for intravenous use in children.

Other medicines and Omeprazole Infusion

Tell your doctor, nurse or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. This is because Omeprazole Infusion can affect the way some medicines work and some medicines can have an effect on Omeprazole Infusion.

You **must not be given** Omeprazole Infusion if you are taking a medicine containing nelfinavir (used to treat HIV infection).

Tell your doctor, nurse or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus)
- Digoxin (used to treat heart problems)
- Diazepam (used to treat anxiety, relax muscles or in epilepsy)
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Omeprazole Infusion
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Omeprazole Infusion.
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots (thrombi))
- Erlotinib (used to treat cancer)
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Omeprazole Infusion treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Omeprazole Infusion to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before you are given this medicine.

Omeprazole is excreted in breast milk but it is not likely to influence the child when therapeutic doses are used. Your doctor will decide whether you can take Omeprazole Infusion if you are breast-feeding.

Driving and using machines

Omeprazole Infusion is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

Omeprazole Infusion contains sodium

This medicine contains less than 1mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How Omeprazole Infusion is given to you

Omeprazole Infusion can be given to adults including the elderly. There is limited experience with Omeprazole Infusion for intravenous use in children.

Being given Omeprazole Infusion

- Omeprazole Infusion will be given to you by a doctor who will decide how much you need
- The medicine will be given to you as an infusion into one of your veins

If you are given more Omeprazole Infusion than you should

If you think you have been given too much Omeprazole Infusion, talk to your doctor straight away.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following rare but serious side effects, stop using Omeprazole Infusion and contact a doctor immediately.

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction)
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Other side effects include.

Common side effects (may affect up to 1 in 10 people)

- Effects on your stomach or gut: diarrhoea, stomach pain, constipation, wind (flatulence)
- Headache
- Feeling sick (nausea) or being sick (vomiting)
- Benign polyps in the stomach.

Uncommon side effects (may affect up to 1 in 100 people)

- Swelling of the feet and ankles
- Disturbed sleep (insomnia)
- Spinning feeling (vertigo)
- Changes in blood tests that check how the liver is working

- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy
- Skin rash, lumpy rash (hives) and itchy skin
- Generally feeling unwell and lacking energy.

Rare side effects (may affect up to 1 in 1,000 people)

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed
- Taste changes
- Eyesight problems such as blurred vision
- Suddenly feeling wheezy or short of breath (bronchospasm)
- Dry mouth
- An inflammation of the inside of the mouth
- An infection called “thrush” which can affect the gut and is caused by a fungus
- Hair loss (alopecia)
- Skin rash on exposure to sunshine
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness
- Joint pains (arthralgia) or muscle pains (myalgia)
- Severe kidney problems (interstitial nephritis)
- Increased sweating.

Very rare side effects (may affect up to 1 in 10,000 people)

- Changes in blood count including agranulocytosis (lack of white blood cells)
- Aggression
- Seeing, feeling or hearing things that are not there (hallucinations)
- Severe liver problems leading to liver failure and inflammation of the brain
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Muscle weakness
- Enlarged breasts in men.

Side effects with unknown frequency (frequency cannot be estimated from the available data)

- Inflammation of the gut which causes diarrhoea
- Rash, possibly with pain in the joints
- If you are on Omeprazole Infusion for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness or increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Irreversible visual impairment has been reported in isolated cases of critically ill patients who have received omeprazole intravenous injection, especially at high doses, but no causal relationship has been established.

Omeprazole infusion may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must **consult your doctor as soon as possible** so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE OMEPRAZOLE INFUSION

Keep this medicine out of the sight and reach of children.

Do not use Omeprazole Infusion after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the vial in the outer container.

Shelf life after reconstitution: 12 hours after reconstitution with 0.9% sodium chloride solution and 6 hours after reconstitution with 5% glucose solution. From a microbiological point of view, the product should be used immediately unless it has been reconstituted under controlled and validated aseptic conditions.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Omeprazole Infusion contains

- The active substance is omeprazole. Each vial of powder contains omeprazole sodium equivalent to 40 mg of omeprazole
- The other ingredients are disodium edetate and sodium hydroxide.

What Omeprazole Infusion looks like and contents of the pack

Omeprazole 40 mg powder for solution for infusion comes in a vial.

The dry powder in the vial is made into a solution before it is given to you.

Pack sizes: 5 vials.

Marketing Authorisation Holder

Ibigen Srl. Via Fossignano, 2, 04011 Aprilia (LT), Italy

Manufacturer

Sofarimex Industria Química e Farmaceutica Lda, Agualva-2735-213, Cacém, Portugal

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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only:

The entire contents of each vial should be dissolved in approximately 5 ml and then immediately diluted to 100 ml. Sodium chloride 9 mg/ml (0.9%) solution for infusion or glucose 50 mg/ml (5%) solution for infusion must be used. The stability of omeprazole is influenced by the pH of the solution for infusion, which is why no other solvent or quantities should be used for dilution.

Preparation

1. With a syringe draw 5 ml of infusion solution from the 100 ml infusion bottle or bag
2. Add this volume to the vial with the freeze-dried omeprazole, mix thoroughly making sure all omeprazole is dissolved
3. Draw the omeprazole solution back into the syringe
4. Transfer the solution into the infusion bag or bottle

5. Repeat steps 1-4 to make sure all omeprazole is transferred from the vial into the infusion bag or bottle.

Alternative preparation for infusions in flexible containers

1. Use a double-ended transfer needle and attach to the injection membrane of the infusion bag
Connect the other needle-end from the vial with freeze-dried omeprazole
2. Dissolve the omeprazole substance by pumping the infusion solution back and forward between the infusion bag and the vial
3. Make sure all omeprazole is dissolved.

The solution for infusion is to be administered in an intravenous infusion for 20-30 minutes.

Dosage

40 mg once daily is recommended. In patients with Zollinger-Ellison Syndrome, 60 mg once daily is the recommended starting dose. Doses exceeding 60 mg daily should be divided and given twice daily.

Hepatic impairment: A daily dose of 10-20 mg may be sufficient.