

PACKAGE LEAFLET

Package leaflet: Information for the user

Omeprazole 40 mg Powder for solution for infusion

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Omeprazole is and what it is used for

Omeprazole powder for solution for 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 powder for solution for infusion can be used as an alternative to oral therapy.

2. What you need to know before Omeprazole is given to you

You must not be given Omeprazole:

- 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).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Omeprazole, if:

- You have ever had a skin reaction after treatment with a medicine similar to Omeprazole that reduces stomach acid
- You are due to have a specific blood test (Chromogranin A).

Omeprazole may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you are given Omeprazole 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.

This medicine may affect the way that your body absorbs vitamin B₁₂, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B₁₂:

- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

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. Remember to also mention any other ill-effects like pain in your joints.

Monitoring Tests

If you take Omeprazole on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking a proton pump inhibitor like Omeprazole, especially over a period of more than one year, may slightly increase your risk of fracture of 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).

Other medicines and Omeprazole

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Omeprazole can affect the way some medicines work and some medicines can have an effect on Omeprazole.

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

Tell your doctor 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
- 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
- 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 treatment.

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

If you are going into hospital for any other tests, talk to your doctor as you may need to stop taking this medicine for a short while.

Pregnancy and breast-feeding

Pregnancy

Before you are given Omeprazole, tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can be given Omeprazole during this time.

Breast-feeding

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

Driving and using machines

Omeprazole 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 contains sodium

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

3. How Omeprazole will be given:

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

Being given Omeprazole:

- Omeprazole 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 than you should

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

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 and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties to swallow (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):

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

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

- Swelling of the feet and ankles
- Disturbed sleep (insomnia)
- Dizziness, tingling feelings such as “pins and needles”, feeling sleepy
- Spinning feeling (vertigo)
- Changes in blood tests that check how the liver is working
- Skin rash, lumpy rash (hives) and itchy skin
- Generally feeling unwell and lacking energy
- Fracture of the hip, wrist or spine.

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
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness
- Hair loss (alopecia)
- Skin rash on exposure to sunshine
- Joint pains (arthralgia) or muscle pains (myalgia)
- Severe kidney problems (interstitial nephritis)
- Increased sweating
- Inflammation in the gut (leading to diarrhoea).

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.

Not known side effects (frequency cannot be estimated from the available data):

- Rash, possibly with pain in the joints
- If you are on Omeprazole 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, 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 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.

Do not be concerned by this list of possible side effects. You may not get any of them

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Omeprazole

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

Do not use this medicine after the expiry date which is stated on the vial and on the box. The expiry date refers to the last day of that month.

Before opening: Do not store above 25°C. Store in the original package in order to protect from light.

After reconstitution:

Chemical and physical in-use stability has been demonstrated for 12 hours after reconstitution in 0.9% sodium chloride and for 6 hours after reconstitution in 5% glucose at 25°C.

However, from a microbiological point of view, the product should be used immediately after reconstitution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Omeprazole contains

The active substance is omeprazole. Each vial of powder contains 42.5 mg of omeprazole sodium equivalent to 40 mg of omeprazole.

The other ingredients are: Disodium edetate, sodium hydroxide.

What Omeprazole looks like and contents of the pack

This medicine is available as a powder for solution for infusion in a 6 ml vial. A box contains 5 or 10 vials.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer

Mylan S.A.S. 117 Allée des Parcs, 69800 Saint-Priest, France

Or

Sirton Pharmaceuticals S.p.A. - Piazza XX Settembre, 2 - 22079 Villa Guardia (CO) - Italy

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The following information is intended for healthcare professionals only:

Preparation of the infusion

The entire contents of each vial is to 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.

Any unused product or waste material should be disposed of in accordance with local requirements.