**Package leaflet: Information for the user**

**[Invented name] 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 or pharmacist.
- 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 [Invented name] is and what it is used for

[Invented name] 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.

[Invented name] in the form of powder for solution for infusion can be used in adults as an alternative to oral therapy.

## 2. What you need to know before [Invented name] is given to you

**You must not be given [Invented name]**
- If you are allergic (hypersensitive) 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 [Invented name] 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**
Talk to your doctor, nurse or pharmacist before taking [Invented name].

Serious skin reactions, including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), and acute generalized pustular eruption (AGEP) have been reported in association with treatment with omeprazol. If you notice any symptoms related to these severe skin reactions described in section 4, stop using [Invented name] and seek medical attention immediately.

[Invented name] may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you are given [Invented name] 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 have ever had a skin reaction after treatment with a medicine similar to [Invented name] that reduces stomach acid.
- You are due to have a specific blood test (Chromogranin A).

Taking a proton pump inhibitor like [Invented name], 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).

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 [Invented name]. Remember to also mention any other ill-effects like pain in your joints.

When taking omeprazole, inflammation in your kidney may occur. Signs and symptoms may include decreased volume of urine or blood in your urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report such signs to the treating physician.

**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 [Invented name]**
Please tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This is because [Invented name] can affect the way some medicines work and some medicines can have an effect on [Invented name].

You must not be given [Invented name] 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 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 [Invented name].
- 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 [Invented name].
- 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 [Invented name] treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as [Invented name] 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**
Before you are given [Invented name], tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can be given [Invented name] during this time.

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 [Invented name] if you are breastfeeding.

Animal studies with the omeprazole, do not indicate effects with respect to fertility.

**Driving and using machines**
[Invented name] 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.

**[Invented name] contains sodium**
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially "sodium free".
The entire contents of each vial is to be dissolved and diluted. Any sodium present in diluent should be taken into account when calculating the total sodium content in the prepared dilution. For detailed information of sodium content in the diluent refer to the Product Information provided by the manufacturer.

## 3. How [Invented name] is given to you

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

**Being given [Invented name]**
- [Invented name] 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 [Invented name] than you should**
If you think you have been given too much [Invented name], 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 or very rare but serious side effects, stop using [Invented name] 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) - rare
- 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' - very rare
- A widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome) - rare
- A red, scaly, widespread rash with bumps under the skin and blisters, accompanied by a fever. Symptoms usually appear at the beginning of treatment (acute generalized pustular eruption) - rare
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems - rare.

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)
- 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)
- 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.

**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
- DRESS syndrome or drug hypersensitivity syndrome, acute generalized pustular eruption
- 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.

**Frequency not known (frequency cannot be estimated from the available data)**
- If you are on [Invented name] 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 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.
- rash, possibly with pain in the joints.

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

[Invented name] 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store [Invented name]

This medicine does not require any special temperature storage conditions.~~Store below 25 °C.~~
Keep the vials in the outer carton in order to protect from light.

Shelf life after reconstitution:
Solution for infusion reconstituted with sodium chloride 9 mg/ml (0.9%) should be used within 12 hours after preparation.
Solution for infusion reconstituted with glucose 50 mg/ml (5%) should be used within 6 hours after preparation.
From a microbiological point of view, the product should be used immediately unless it has been reconstituted under controlled and validated aseptic conditions.

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

Do not use this product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

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 [Invented name] contains**
- The active ingredient is omeprazole. Each vial of powder for solution for infusion contains 42.6 mg omeprazole sodium equivalent to 40 mg omeprazole.
- The other ingredients are sodium hydroxide and disodium edetate.

**What [Invented name] 40 mg looks like and contents of the pack**
[Invented name] is white or most white, porous and uniform lyophilized powder for solution for infusion (powder for infusion) supplied in a colourless type I glass vial with a 10 ml capacity. It is closed with a chlorobutyl rubber stopper and sealed with an aluminum flip-off cap.
In its dissolved form it is a clear liquid, practically free from visible particles.
Pack sizes: 5 vials x 40 mg, 10 vials x 40 mg, 50 vials x 40 mg

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder
[To be completed nationally]

Manufacturer
[To be completed nationally]

**This medicine is authorised in the Member States of the European Economic Area:**
<{Name of the Member State}> <{Name of the medicine}>
<{Name of the Member State}> <{Name of the medicine}>

**This leaflet was last revised in**

---

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