Package leaflet: Information for the patient

Omeprazol Sandoz® infuus 40, poeder voor oplossing voor intraveneuze infusie 40 mg

Omeprazole sodium

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 [nationally completed name] is and what it is used for

[Nationally completed 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.

[Nationally completed name] powder for solution for infusion can be used as an alternative to oral therapy.

2. What you need to know before [nationally completed name] is given to you

You must not be given [nationally completed name]
- 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).

Do not use [nationally completed 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 you are given [nationally completed name].

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and acute generalized exanthematous pustulosis (AGEP) have been reported in association with [nationally completed name] treatment. Stop using [nationally completed name] and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

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

Taking a proton pump inhibitor like [nationally completed 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).

This medicine contains less than 1 mmol sodium (23 mg) per 40 mg dose. This means it is essentially "sodium- free".

Children and adolescents
Do not give this medicine to children and adolescents under 18 years of age. There is limited experience with [nationally completed name] for intravenous use in children.

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

You must not be given [nationally completed name] 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 [nationally completed 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 [nationally completed 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 [nationally completed name] treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as [nationally completed 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 and breast-feeding
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 taking this medicine.

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 [nationally completed name] if you are breast-feeding.

Driving and using machines
[nationally completed 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.

3. How [nationally completed name] is given to you

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

Being given [nationally completed name]

- [nationally completed 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 [nationally completed name] than you should
If you think you have been given too much [nationally completed name], 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 (may affect up to 1 in 1,000 people) or very rare (may affect up to 1 in 10,000 people) but serious side effects, stop using [nationally completed 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). The frequency of this side effect is 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'. The frequency of this side effect is very rare.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome). The frequency of this side effect is rare.
- 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). The frequency of this side effect is rare.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. The frequency of this side effect is rare.

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).
- 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.
- Fracture in 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.

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 (frequency cannot be estimated from the available data)
- Inflammation in the gut (leading to diarrhoea).
- If you are on [nationally completed 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 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.
- Rash, possibly with pain in the joints.

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.

[Nationally completed 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 [nationally completed name]

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

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

Do not use [nationally completed name] after the expiry date which is state on the label after EXP. The expiry date refers to the last day of that month.

After preparation of the solution by your doctor or nurse, it must be stored below 25°C and used within 12 hours of reconstitution in the NaCl 0.9% solution or within 6 hours of reconstitution, if a glucose solution has been used.

From a microbiological point of view, the product should be used immediately unless it has been reconstituted under controlled and validated aseptic conditions.

The reconstituted solution should not be used if particles are present. The contents of the vial is meant for single use; any product that has remained in the vial has to be discarded. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What [nationally completed name] contains

Each vial of powder for solution for infusion contains the active ingredient omeprazole sodium, equivalent to 40mg omeprazole.

After reconstitution each 1 ml contains 0.4 mg omeprazole.
Each vial also contains sodium hydroxide and disodium edetate.

Each vial is for one infusion.

What [nationally completed name] looks like and contents of the pack

The powder for solution for infusion is a white to almost white powder.

Omeprazole powder for solution for infusion is available in pack sizes of:
1, 5, 10 and 20 vials

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

Fabrikant
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

In het register ingeschreven onder:
Omeprazol Sandoz infuus 40, poeder voor oplossing voor intraveneuze infusie 40 mg is in het register ingeschreven onder RVG 33439.

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

België	Omeprazol Sandoz 40 mg poeder voor oplossing voor infusie
Bulgarije	Probitor
Tsjechië	ORTANOL, prášek pro přípravu infuzniho roztoku 40 mg /lahvička
Estland	Omeprazole Sandoz
Italië	OMEPRAZOLO SANDOZ BV 40 mg polvere per soluzione per infusione
Letland	Omeprazole Sandoz 40 mg pulveris infūziju šķīduma pagatavošanai
Litouwen	Omeprazole Sandoz 40 mg milteliai infuziniam tirpalui
Nederland	Omeprazol Sandoz infuus 40, poeder voor oplossing voor intraveneuze infusie 40 mg
Portugal	OMEPRAZOL Sandoz 40 mg PÓ PARA SOLUÇÃO PARA PERFUSÃO
Roemenië	Omeprazol Sandoz 40 mg pulbere pentru soluție perfuzabilă
Verenigd Koninkrijk	Omeprazole 40mg Powder for Solution for Infusion

Deze bijsluiter is voor het laatst goedgekeurd in juli 2024

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. After reconstitution the solution is colourless, clear, practically free from visible particles.