

Omeprazole Vianex 40 mg powder and solvent for solution for injection

Omeprazole

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. What Omeprazole Vianex is and what it is used for
2. What you need to know before Omeprazole Vianex is given to you
3. How Omeprazole Vianex is given to you
4. Possible side effects
5. How to store Omeprazole Vianex
6. Further information

1. WHAT OMEPRAZOLE VIANEX IS AND WHAT IT IS USED FOR

Omeprazole Vianex 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 Vianex powder and solvent for solution for injection can be also used as an alternative to oral therapy.

2. WHAT YOU NEED TO KNOW BEFORE OMEPRAZOLE VIANEX IS GIVEN TO YOU

You must not be given Omeprazole Vianex

- If you are allergic (hypersensitive) to omeprazole or any of the other ingredients of Omeprazole Vianex.
- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking medicines containing atazanavir or nelfinavir (used for HIV infection).

If you are not sure, talk to your doctor, nurse or pharmacist before you are given this medicine.

Take special care with Omeprazole Vianex

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

Using other medicines

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

You must not be given Omeprazole Vianex 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 Omeprazole Vianex.
- 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 Vianex.
- 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)).

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Omeprazole Vianex 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

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

Driving and using machines

Omeprazole Vianex 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 OMEPRAZOLE VIANEX IS GIVEN TO YOU

Omeprazole Vianex can be given to adults including the elderly.

There is limited experience with Omeprazole Vianex for intravenous use in children.

Before Omeprazole Vianex is given to you

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

If you are given more Omeprazole Vianex than you should

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Omeprazole Vianex can cause side effects, although not everybody gets them.

If you notice any of the following rare but serious side effects, stop using Omeprazole Vianex 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.

Side effects may occur with certain frequencies, which are defined as follows:

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data.

Other side effects include:

Common side effects

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

Uncommon side effects

- 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

- 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, 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 “candidiasis” 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

- 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.
- Hypomagnesaemia.

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 Vianex 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. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE OMEPRAZOLE VIANEX

Keep out of the reach and sight of children.

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

Store below 25°C.

Keep the container in the outer carton in order to protect from light. Vials can however be stored exposed to normal indoor light outside the box for up to 24 hours.

Shelf life after reconstitution:

The reconstituted solution should be stored below 25°C and should be used within 4 hours after preparation. From a microbiological point of view, the product should be used immediately. Use of other storage conditions are the responsibility of the user and must not exceed 24 hours at 2-8°C, unless reconstitution has taken place under controlled and validated aseptic conditions.

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. FURTHER INFORMATION

What Omeprazole Vianex contains

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

The other ingredients are:

Powder for injection: Sodium hydroxide (for pH adjustment).

Solvent for injection: Citric acid monohydrate (for pH adjustment), macrogol 400, water for injections.

What Omeprazole Vianex looks like and contents of the pack

Omeprazole Vianex 40 mg powder and solvent for solution for injection (powder for injection and solvent for reconstitution of solution for injection) comes in a combination pack consisting of a vial containing dry substance and an ampoule containing solvent.

Pack sizes: 1 vial + 1 ampoule

Marketing Authorisation Holder

VIANEX S.A., Tatoiou str., 146 71 Nea Erithrea, Greece, Tel.: 0030 210 8009111-120

Manufacturer of the lyophilized powder:

VIANEX S.A. – Plant C’
16th km Marathonos Avenue, Pallini, Attiki, Greece

Manufacturer of the solvent and Assembler of the finished product:

VIANEX S.A. – Plant A’
12th km Athens-Lamia National Road, Metamor-phossi, Attiki, Greece

This leaflet was last revised on July 19th, 2012.

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

Omeprazole Vianex solution for injection is obtained by dissolving the freeze-dried substance in the accompanying solvent. No other solvent should be used.

The stability of omeprazole is influenced by the pH of the solution for injection, which is why no other solvents or quantities should be used for dilution. Improperly prepared solutions can be identified by their yellow to brown discolouration and must not be used. Use only clear, colourless or pale yellowish - brown solutions.

Preparation

NOTE: Steps 1 to 5 must be performed in immediate sequence:

1. With a syringe draw all of the solvent from the ampoule (10 ml).
2. Add approximately 5 ml of the solvent to the vial with freeze-dried omeprazole.
3. Withdraw as much air as possible from the vial back into the syringe. This will make it easier to add the remaining solvent.
4. Add the remaining solvent into the vial, make sure the syringe is empty.
5. Rotate and shake the vial to ensure all the freeze-dried omeprazole has dissolved.

Omeprazole Vianex solution for injection must be given only as an intravenous injection and it must not be added to infusion solutions. After reconstitution the injection should be given slowly over a period of at least 2.5 minutes at a maximum rate of 4 ml per minute.