

Omeprazole for Injection 40mg

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1 What Omeprazole is and what it is used for

Omeprazole 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.

- Adults
- Treatment of duodenal ulcers
 - Prevention of relapse of duodenal ulcers
 - Treatment of gastric ulcers
 - Prevention of relapse of gastric ulcers
 - In combination with appropriate antibiotics, *Helicobacter pylori* (*H. pylori*) eradication in peptic ulcer disease
 - Treatment of NSAID-associated gastric and duodenal ulcers
 - Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk
 - Treatment of reflux esophagitis
 - Long-term management of patients with healed reflux esophagitis
 - Treatment of symptomatic gastro-oesophageal reflux disease
 - Treatment of Zollinger-Ellison syndrome.

2 Before Omeprazole is used

You must not be given omeprazole

- If you are allergic (hypersensitive) to omeprazole or any of the other ingredients of Omeprazole
- If you are allergic to other proton pump inhibitor
- medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole)
- If you are taking a medicine containing neflavinir (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

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.

Using other medicines

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
- 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)

Pregnancy and breast-feeding

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. 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 breast-feeding.

Special warnings and precautions for us

In the presence of any alarm symptoms (e.g., significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment may alleviate symptoms and delay diagnosis. Treatment with proton pump inhibitors may lead to slightly increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter*

3 How Omeprazole is used

- 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 injection into one of your veins.

Alternative to oral therapy

In patients where the use of oral medicinal products is inappropriate, Omeprazole 40mg once daily is recommended. In patients with Zollinger-Ellison Syndrome the recommended initial dose of Omeprazole given intravenously is 60 mg daily. Higher daily doses may be required and the dose should be adjusted individually. When doses exceed 60 mg daily, the dose should be divided and given twice daily. Omeprazole 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. For instructions on reconstitution of the product before administration.

Special populations

Impaired renal function

Dose adjustment is not needed in patients with impaired renal function.

Impaired hepatic function

In patients with impaired hepatic function a daily dose of 10-20 mg may be sufficient.

Elderly (> 65 years old)

Dose adjustment is not needed in the elderly.

Paediatric patients

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

Instructions for use and handling

One vial with powder for solution for injection should be mixed with one ampoule containing 10 ml of the solvent for solution for injection. A clear solution should be obtained. Omeprazole Injection should only be dissolved with the solvent for injection provided. No other solvents for intravenous injection should be used. Do not use if any particles are present in the reconstituted solution. The reconstituted solution is for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

4 Possible side effects

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.

• If you are on Omeprazole for more than three months it is possible that the levels of magnesium in your blood may fall.

5 How to store Omeprazole

Keep out of the reach and sight of children. Store in a cool, Dry and dark place.. Store in the original package in order to protect from light. Do not use Omeprazole Injection 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 four hours. 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 What Omeprazole contains:

Each pack contains the active ingredient omeprazole Sodium sterile BP, equivalent to omeprazole 40mg, and one 10 ml FFS ampoule of sterile water for Injections BP

Manufactured in India:

