

PACKAGE LEAFLET: INFORMATION FOR THE USER

UPRONE

Omeprazole for Injection 40 mg and Sodium chloride Injection BP

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.

1. What UPRONE is and what it is used for

UPRONE 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 for injection can be used as an alternative to oral therapy.

2. Before UPRONE 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 nelfinavir (used for HIV infection).

Do not use Omeprazole 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

Take special care with Omeprazole Talk to your doctor, nurse or pharmacist before you are given 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.
- 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 Omeprazole 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 Omeprazole. Remember to also mention any other ill-effects like pain in your joints.

Taking a proton pump inhibitor like Omeprazole Injection, 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).

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age. There is limited experience with Omeprazole for intravenous use in children.

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 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, nurse 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)

- 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

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.

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 Omeprazole if you are breast-feeding.

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.

3. How UPRONE 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.

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.

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, Omeprazole 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.

5. How to store UPRONE

Keep out of the sight and reach of children.

Store in a dry place, below 30°C.

Store in the original package in order to protect from light.

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

6. Further information

What UPRONE contains

Each vial contains omeprazole sodium (Lyophilized), equivalent to omeprazole 40mg.

Each vial is for one injection when mixed with one ampoule containing the diluent for injection.

What Omeprazole looks like and contents of the pack

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

Available Pack Sizes:

1. Single vial pack: Each labeled vial containing Omeprazole for injection is packed in carton along with leaflet.
2. Combipack: Each labelled vial containing Omeprazole for injection is packed along with diluent 10ml ampoule of Sodium Chloride Injection BP in a carton along with leaflet.
3. 25 vial Pack: 25 labelled vials containing Omeprazole for injection are packed in carton along with leaflet.

Marketing Authorisation Holder:

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