

# Omeprazole 40 mg

## Powder for solution for infusion

### 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 or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### In this leaflet:

1. Serious side effects
2. What Omeprazole 40 mg is and what it is used for
3. Before you take Omeprazole 40 mg
4. How you take Omeprazole 40 mg
5. Possible side effects
6. How to store Omeprazole 40 mg
7. Further information

#### 1. SERIOUS SIDE EFFECTS

If you notice any of the following rare but serious side effects, stop using Omeprazole 40 mg 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.

#### 2. WHAT Omeprazole 40 mg IS AND WHAT IT IS USED FOR

##### - Pharmacotherapeutic group:

Omeprazole 40 mg contains the active substance omeprazole. It belongs to a group of medicines called 'proton pump inhibitors'. It works by reducing the amount of acid that your stomach produces.

##### - Therapeutic indications:

Omeprazole 40 mg is a Gastric anti-secretory treatment when the oral route is impossible.

#### 3. Before you take Omeprazole 40 mg

##### Do not take Omeprazole 40 mg:

- If you are allergic (hypersensitive) to omeprazole or any of the other ingredients of Omeprazole 40 mg.
- 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).
- If you are not sure of your doctor, nurse or pharmacist before you are given this medicine.

##### b. Take special care with Omeprazole 40 mg

Omeprazole 40 mg may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you are given Omeprazole 40 mg 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.
- **Solidus cutaneous lupus erythematosus (SCLC):** Proton pump inhibitors are associated with very frequent cases of SCLC. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping this medication. SCLC after previous treatment with a proton pump inhibitor may increase the risk of SCLC with other proton pump inhibitors.

##### c. Using other medicines, herbal or dietary supplements

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 40 mg can affect the way some medicines work and some medicines can have an effect on Omeprazole 40 mg. You must not be given Omeprazole 40 mg 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:

- Ketconazole, 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 while you start or stop taking Omeprazole 40 mg.
- 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 40 mg.
- 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).
- Cimetidine (used to treat intermittent acidification).
- Saquinavir (used to treat HIV infection).
- Clopidogrel (used to prevent blood clots (thrombi)).
- Erolitinib (used to treat cancer).

• Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methyl, your doctor may temporarily stop your Omeprazole 40 mg treatment.

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Omeprazole 40 mg to treat ulcers caused by Helicobacter pylori infection, it is very important that you tell your doctor about any other medicines you are taking.

#### d. Taking Omeprazole 40 mg with food and drink

Without object.

##### e. Pregnancy and breast-feeding

Before you are given Omeprazole 40 mg, tell your doctor if you are pregnant or trying to get pregnant. Your doctor will decide whether you can be given Omeprazole 40 mg during this time.

Your doctor will decide whether you can take Omeprazole 40 mg if you are breastfeeding.

##### f. Driving and using machines

Omeprazole 40 mg 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.

##### g. Important information about some of the ingredients of Omeprazole 40 mg

Without object.

#### 4. How to take Omeprazole 40 mg

Always take Omeprazole 40 mg exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

- Omeprazole 40 mg can be given to adults including the elderly.
- There is limited experience with Omeprazole 40 mg for intravenous use in children.

##### Being given Omeprazole 40 mg

- Omeprazole 40 mg will be given to you by a doctor who will decide how much you need.
- The medicine will be given to you as infusion into one of your veins.

##### a. If you take more Omeprazole 40 mg than you should

If you think you have been given too much Omeprazole 40 mg, talk to your doctor straight away.

##### b. If you forget to take Omeprazole 40 mg

Without object.

##### c. If you stop taking Omeprazole 40 mg

Without object.

#### 5. POSSIBLE SIDE EFFECTS

Like all medicines, Omeprazole 40 mg can cause side effects, although not everybody gets them.

- 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 1000

Rare: affects 1 to 10 users in 10000

Very rare: affects less than 1 user in 10000

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 being sick (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, 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

- 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.
- Hypogonadism.

#### Irreversible visual impairment has been reported in isolated cases of critically ill patients who have received Omeprazole 40 mg intravenous infusion, especially at high doses, but no causal relationship has been established at this time.

- Omeprazole 40 mg 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.

#### 6. HOW TO STORE Omeprazole 40 mg

- Keep out of the reach and sight of children.
- Do not store above 30°C. Store in the original package in order to protect from light.
- Omeprazole 40 mg 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.
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#### 7. FURTHER INFORMATION

##### a. What Omeprazole 40 mg contains:

- The active substance is omeprazole sodium equivalent to 40 mg of omeprazole.
- The other ingredients are: Sodium hydroxide, Disodium edetate.

##### b. What Omeprazole 40 mg looks like and contents of the pack

Omeprazole 40 mg powder for solution for infusion, is available in one presentation.

Omeprazole 40 mg powder for solution for infusion is a slight yellowish cake.

##### c. Marketing Authorisation Holder and Manufacturer:

LES LABORATOIRES MEDIS - S.A.

Route de Tunis - KM 7 - BP 206 - 8000 Nabeul - Tunisie

Tel: (216) 72 23 51 06

Fax: (216) 72 23 51 06

E-mail: marketing.ventes@medis.com.tn

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

Salehiya Trading Establishment

(Medical equipment & pharmaceuticals)

P.O.Box: 991, Riyadh 11421- Kingdom of Saudi Arabia

Tel: 00 966 1 46 46 955

Fax: 00 966 1 46 34 362

E-mail: pharma@salehiya.com

• To report any side effect(s):

• **Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC)

o Fax: +966-11-205-7662

o Call NPC at +966-11-2038222, Exts: 5193-2317-2356-2340.

o Toll free phone: 8002490000

o E-mail: npc.drug@sfd.a.gov.sa

o Website: www.sfd.a.gov.sa/npc

#### • Other GCC states:

- Please contact the relevant competent authority.

#### f. Council of Arab Health Ministers

##### THIS IS A MEDICATION

- Medication is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

- Keep all medications out of reach of children

Council of Arab Health Ministers  
Union of Arab Pharmacists

g. This patient information leaflet is approved by the Saudi Food and Drug Authority



