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PACKAGE LEAFLET: INFORMATION FOR THE USER

OMEPRAZOLE TEVA 40 mg POWDER FOR SOLUTION FOR INFUSION

omeprazole

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Omeprazole Teva is and what it is used for
2. What you need to know before you are given Omeprazole Teva
3. How Omeprazole Teva is given
4. Possible side effects
5. How to store Omeprazole Teva
6. Contents of the pack and other information

1 WHAT OMEPRAZOLE TEVA IS AND WHAT IT IS USED FOR

Omeprazole Teva 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 Teva 40 mg powder for solution for infusion can be used as an alternative to oral therapy.

2 WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN OMEPRAZOLE TEVA

You must NOT be given Omeprazole Teva:

- 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).

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

Warnings and precautions

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

Taking a proton pump inhibitor like omeprazole, 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).

- You have reduced body stores or risk factors for reduced vitamin B₁₂ and receive omeprazole long-term treatment. As with all acid reducing agents, omeprazole may lead to a reduced adsorption of vitamin B₁₂.

Other medicines and Omeprazole Teva

Please tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Omeprazole Teva can affect the way some medicines work and some medicines can have an effect on Omeprazole Teva.

You must not be given Omeprazole Teva 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, 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 Omeprazole Teva
- 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 Teva
- Rifampicin (used to treat tuberculosis)
- Atazanavir and nelfinavir (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 for certain types of cancer)
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methothrexate, your doctor may temporarily stop your Omeprazole treatment.

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

Omeprazole may interfere with some tests (chromogranin A). To avoid this interference the omeprazole should be temporarily stopped five days before testing.

Pregnancy and breast-feeding

Before you are given Omeprazole Teva, tell your doctor if you are pregnant, think you may be pregnant or are planning to have a baby. Your doctor will decide whether you can be given Omeprazole Teva during this time.

Your doctor will decide whether you can take Omeprazole Teva if you are breast-feeding.

Driving and using machines

Omeprazole Teva 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.

Omeprazole Teva contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium free".

3 HOW OMEPRAZOLE TEVA IS GIVEN

- Omeprazole Teva can be given to adults including the elderly

Children

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

Being given Omeprazole Teva

- Omeprazole Teva 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 Omeprazole Teva than you should

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

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 but serious side effects, stop using Omeprazole Teva 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.

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

Special precautions for disposal and other handling

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.

Use in one patient for one treatment only.

Do not use if any particles are present in the reconstituted solution.

Preparation

1. With a syringe draw 5 ml of infusion solution from the infusion bag (PVC).
2. Add this volume to the vial with the freeze-dried omeprazole, mix thoroughly making sure all omeprazole is dissolved.

The above side effects, which are serious and require medical attention, are 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).

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 of 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.
- Inflammation of the bowel.

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
- If you are on omeprazole 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.

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 Teva 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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5 HOW TO STORE OMEPRAZOLE TEVA

- **Keep this medicine out of the sight and reach of children**
- Do not use Omeprazole Teva after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month
- Store in the original package in order to protect from light
- *Shelf life after reconstitution:*
 - Solution for infusion reconstituted with sodium chloride 9 mg/ml (0.9%) should be used within 12 hours after preparation.
 - Solution for infusion reconstituted with glucose 50 mg/ml (5%) should be used within 6 hours after preparation.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6 CONTENTS OF THE PACK AND OTHER INFORMATION

What Omeprazole Teva contains

- The active substance is omeprazole. Each vial of powder for solution for infusion contains 42.6 mg omeprazole sodium equivalent to 40 mg of omeprazole.
- The other ingredients are sodium hydroxide and disodium edetate.

What Omeprazole Teva looks like and contents of the pack
Omeprazole Teva 40 mg powder for solution for infusion is a white powder and comes in a vial.

The dry powder in the vial is made into a solution before it is given to you. The reconstituted product is clear and free from visible particles.

This medicine is available in two pack-sizes: 1 or 5 glass vials packed in folded carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.,
Computerweg 10,
3542 DR Utrecht,
The Netherlands.

Manufacturer

SIRTON PHARMACEUTICALS SpA.,
Piazza XX Settembre, 2
22079 Villa Guardia (CO)
Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland	Omeprazole Teva 40 mg powder for solution for infusion
Netherlands	Omeprazol 40 mg PCH, poeder voor oplossing voor infusie
United Kingdom	Omeprazole 40 mg powder for solution for infusion

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3. Draw the omeprazole solution back into the syringe.
4. Transfer the solution into the infusion bag (PVC).
5. Repeat steps 1-4 to make sure all omeprazole is transferred from the vial into the infusion bag (PVC).

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.