PATIENT INFORMATION LEAFLET

OMEPREFUL 40 mg powder and solvent for solution for IV injection
Administered intravenously.
Sterile

- ***Active substance:*** Omeprazole sodium (Equivalent to 40 mg omeprazole)
- ***Excipients:*** Sodium hydroxide (to adjust pH), citric acid monohydrate, polyethylene glycol, water for injection

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION 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.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use* ***higher or lower*** *dose other than your recommended dose.*

The following subjects are covered here in:

1. What is OMEPREFUL and what it is used for?

OMEPREFUL is known as a "proton pump inhibitor". Reduces acid formation in your stomach.

OMEPREFUL consists of a small glass bottle (vial) and solvent ampoule. Each vial contains 42.6 mg of omeprazole sodium, equivalent to 40 mg of omeprazole. Each ampoule contains solvent for injection.

Your medication is used to treat the following conditions:
• Inflammation and pain in the esophagus due to acid escaping from the stomach to the esophagus (in reflux esophagitis and esophageal reflux disease),
• Ulcer (duodenal ulcer) in the upper part of the intestines, ulcer in the esophagus (peptic ulcer) or ulcer (gastric ulcer) in the stomach,
• Gastric ulcer caused by non-steroidal anti-inflammatory (hormone-free anti-inflammatory) drugs and ulcers in the upper part of the intestines,

• Zollinger-Ellison syndrome, in the case of excessive acid in the stomach.

2. Before you are given OMEPREFUL

DO NOT USE OMEPREFUL under the following circumstances:
If:
- If you are allergic to omeprazole or any of the other ingredients of OMEPREFUL,
- If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole) (during treatment with these drugs, Salmonella and Campylobacter can cause a slight increase in the risk of gastrointestinal infection.),
- If you are taking a medicine containing nelfinavir (Used to treat HIV infection)

USE OMEPREFUL CAREFULLY in the following cases If:
- Pain or indigestion occurs during treatment with OMEPREFUL,
- There is significant weight loss out of your control,
- You begin to vomit food or blood,
- You pass black stools (melena)(blood-stained faeces),
- You have severe liver problems,
- You have a fracture risk due to osteoporosis (bone resorption) in the hip, wrist or spine,
- The amount of magnesium in your blood is low and you are being treated for it (for instance if you use drugs that can reduce the amount of magnesium in your blood, such as digoxin or diuretics, your doctor will periodically want to monitor the magnesium levels in your blood).
- You're going for a diagnostic examination for neuroendocrine tumors.

IMMEDIATELY consult your doctor.

If these warnings apply or applied to you, please consult your physician.

Using OMEPREFUL with food and beverages

OMEPREFUL has no interaction with food and beverages.

Pregnancy
Please consult your physician or pharmacist before taking the drug.

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

If you realize that you are pregnant during your treatment, immediately consult your physician or pharmacist.

Lactation
Please consult your physician or pharmacist before taking the drug.

Your doctor will decide whether you can take OMEPREFUL if you are breastfeeding.

Ability to drive and use machines
OMEPREFUL is not expected to affect your ability to drive and use machines. Side effects

such as dizziness and visual disturbances may occur (see section 4). If these kind of adverse affects are occurred during your treatment, you should not drive or use machines.
Vital information regarding some of the excipients contained in OMEPREFUL
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is essentially "sodium free".

Use in combination with other drugs

- Drugs to prevent fungal infections (itraconazole, ketoconazole posaconazole, voriconazole),
- Anxiety medication (diazepam)
- Epilepsy medication (phenytoin),
- Blood clotting medications (warfarin or other vitamin K blockers),
- Intermittent claudication (pain, tension and weakness in the legs when walking) medications (cilostazol),
- Medication used in transplant patients (tacrolimus),
- Heart medication (digoxin),
- The medication used in the treatment of tuberculosis (rifampicin),
- The medication used to prevent blood clots (clopidogrel),
- Interaction with the drug (erlotinib) used in the treatment of cancer may occur.
- If you are taking a high dose of chemotherapy medication (methotrexate) in the treatment of cancer, your doctor may temporarily stop your OMEPREFUL treatment.
- It is not recommended that omeprazole be used concurrently with certain drugs such as, cavavir, atazanavir and nelfinavir used for the treatment of HIV.
- If you have serious liver problems, tell your doctor that dose reduction may be necessary.

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.

If you are currently taking or recently took any prescribed or over-the-counter drugs, please inform your physician or pharmacist.

3. How you will be given OMEPREFUL
Instructions regarding correct use and dosage/administration frequency:

The usual dose is 40 mg once a day.

In patients with Zollinger-Ellison Syndrome (a condition that causes excess acid secretion in the stomach) the recommended initial dose of Omeprazole is 60 mg daily.

Higher doses may be required and the dose should be adjusted individually. The dose will be determined by the doctor.

Method of administration:
A doctor or nurse will apply the OMEPREFUL slowly into your vein.

Various age groups:

- **Use in children:**

There is limited experience with Omeprazole for use in children.

- **Use in the elderly:**

Dose adjustment is not required in elderly patients.

Special usage cases:

OMEPREFUL can be administered orally to patients who cannot use capsules or tablets and to patients fed to the tube.

Hepatic failure:

Lower doses may be necessary in patients with hepatic impairment.

Renal failure:

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

Depending on your disease, your doctor will determine the dose of your medicine and administer to you.

If you are under the impression that the effect OMEPREFUL is too strong or weak, consult your physician or pharmacist.

If you have taken more OMEPREFUL than you should have:

If you have used OMEPREFUL more than you should have or more than prescribed, consult a physician or a pharmacist.

If you forget to take OMEPREFUL

Do not double-dose to make up for forgotten doses..

Possible effects once OMEPREFUL treatment is concluded

There is no effect.

4. Possible side effects

Like all medicines, OMEPREFUL may have side effects in people who are sensitive to the substances contained in its contents.

If you notice any of the following rare but serious side effects, stop using OMEPREFUL and talk to your doctor immediately or contact the emergency department of the hospital nearest you:

- Allergic reactions such as swelling of face, lips, tongue and / or throat, difficulty in breathing, difficulty in swallowing (anaphylactic shock),
- Very serious skin reactions, known as Stevens-Johnson syndrome, seen as skin disorders in the form of an inflamed wound or water blister,
- Symptoms of liver problems such as yellow skin, dark urine and fatigue.

If you have one of these, you have a serious allergy to OMEPREFUL. You may need immediate medical intervention or hospitalization.

All of these very serious side effects are very rare.

The side effects in this section are classified according to their frequency. For this purpose, the following frequency definitions are used.

Side effects are listed in the following categories:

Very common: It can be seen in at least 1 of 10 patients.
Common: Less than one in 10 patients, but more than one in 100 patients.
Uncommon: Less than one in 100 patients, but more than one in 1000 patients.
Rare: Less than one in 1000 patients.
Very rare: Less than one in 1000 patients.
Not known: Unable to predict based on available data.

Common:
- Headache
- Effects on your stomach or gut: diarrhea, constipation, abdominal pain, formation of gas in the stomach
- Feeling sick (nausea) or being sick (vomiting).
- Benign polyps in the stomach

Uncommon:
- Swelling of the feet and ankles
- Disturbed sleep (insomnia)
- Dizziness, tingling feelings, feeling sleepy
- Spinning feeling (vertigo)
- Changes in blood tests which are performed to check how the liver is working
- Rash, skin inflammation and / or pruritus, urticaria
- Generally feeling unwell and lack of energy

Rare:
- Agitation (uneasiness), irritability, depresssion
- Dry mouth, inflammation of the inside of the mouth
- Fungal infection in the gastrointestinal tract
- Reduction in the number of cells in the blood (leukopenia, thrombocytopenia, agranulocytosis, pancytopenia)
- Serious liver problems (interstitial nephritis)
- Liver inflammation without hepatitis or jaundice, liver failure
- Pain in the muscles, muscle weakness and pain in the joints
- Sensitivity to light, serious skin reactions
- Hair loss (alopecia)
- Hypersensitivity reactions (angioedema, fever, bronchospasm and anaphylactic shock)
- Increased sweating
- Blurred vision, taste disorder
- Decreased blood sodium level (may cause weakness, vomiting and cramps)

Very rare:
- 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
- Muscle weakness

- Enlarged breasts in men
- 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)

Not known:
- Intestinal inflammation (may cause diarrhea)
- Decrease in the amount of magnesium in the blood (if you have been treated with OMEPREFUL for more than 3 months, your amount of magnesium in your blood may be reduced. Please tell your doctor immediately that the low amount of magnesium may cause a decrease in the amount of potassium and calcium in your blood. Your doctor may ask you to have regular blood tests to monitor your magnesium level.

In patients with severe disease, irreversible visual disturbances have been reported in a few cases, especially after intravenous treatment of high doses of omeprazole. However, a causal relationship between these symptoms and omeprazole treatment could not be established.

OMEPREFUL 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.

If you notice any side effect not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store OMEPREFUL

Keep the OMEPREFUL out of the sight and reach of children, and in its original package.

Store at room temperature below 25ºC, protected from light.

The vials removed from the outer package can be stored for up to 24 hours under normal room light, provided they are protect from light.

The prepared injection solution can be stored for 4 hours at 25°C and 12 hours at the refrigerator.

Your doctor or hospital will maintain your OMEPREFUL. The correct storage, preparation and application of OMEPREFUL is the responsibility of the health personnel.

Use in accordance with expiration dates.

Do not use OMEPREFUL after the expiration date printed on its packaging. If you notice any irregularities in the product and/or its packaging, do not use OMEPREFUL.

Any unused product or waste material must be disposed of in accordance with local requirements.

Do not throw away any expired or unused medicines! Give to the collection system determined

by the Ministry of Environment and Urbanization.

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These instructions were approved on 10.04.2020

THE FOLLOWING INFORMATION IS FOR THE HEALTH PERSONNEL WHO WILL APPLY THIS MEDICATION

I.V. Injection:

OMEPREFUL should be injected slowly via intravenous. The solution should only be prepared with 10 ml of solvent in its packaging (no other solvent should be used).

If the preparation is made incorrectly, discoloration may occur. After the preparation, the injection should be performed in a minimum of 2.5 minutes, as to be a maximum of 4 ml per minute.

The solution can be stored at room temperature for up to 4 hours, in refrigerator for 12 hours after preparation.