IPPROTON ® 40 mg, powder for injection

Read this entire leaflet carefully before you start taking 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 or pharmacist.
•This medicine has been prescribed for you only.. Do not pass it on to others.. It may harm them, even if their signs of illness are the same as yours.
•If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What is IPPROTON 40 mg, Powder for injection AND in which case is it used ?

IPPROTON 40 mg, Powder for injection contains active substance of omeprazole. It belongs to the class of medications called proton pump inhibitors. It decreases the amount of acid produced by the stomach.
IPPROTON 40 mg, Powder for injection may be taken as an alternative to oral treatment.

2. What you need to know before you take IPPROTON 40 mg, Powder for injection ?

Do not take IPPROTON 40 mg, Powder for injectionif:
• you are allergic to omeprazole or to any other ingredient contained in the medicine mentioned in section 6.
• you are allergic to another proton pump inhibitor (ex : pantoprazole, lanzoprazole, rabeprazole, esomeprazole).
• you take medicines containing nelfinavir (taken for HIV).

Warnings and precautions
Tell your doctor, pharmacist or nurse before you take IPPROTON 40 mg, Powder for injection if :
• You have ever had a skin reaction after treatment with a medicine similar to IPPROTON 40 mg Powder for injection to reduce stomach acid.
• You are due to have a specific Blood test (ChromograninA).
IPPROTON 40 mg Powder for injection may hide symptoms of other diseases. Therefore, before you start taking IPPROTON 40 mg Powder for Injection or while on treatment, you should tell your doctor immediately if any of the following symptoms occurs:
• You lose weight for no reason or if you have problems swallowing.
• You have stomach pain or indigestion.
• You vomit food or blood.
• You have black stools tinged with blood.
• You have severe or persistent diarrhea because omeprazole has been associated with a small increase in infectious diarrhea.
• If you have severe liver problems.
If you develop a rash, especially in areas exposed to the sun, consult your doctor as soon as possible, as you may need to stop taking IPPROTON 40 mg Powder for injection. Do not forget to mention any other harmful effects, such as pain in your joints.
Monitoring Exams
If you take IPPROTON for a long-term (longer than one year), your doctor will probably monitor you on a regular basis.You must accurately define all new or exceptional symptoms and events when you see your doctor.
Taking a proton pump inhibitor such as IPPROTON 40 mg Powder for Injection, especially over a period longer than one year, may slightly increase the risk of fracture of the hip, wrist or vertebrae. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which may increase the risk of osteoporosis).

Children and adolescents
Not Applicable.

Other medicines and IPPROTON 40 mg, powder for injection
Tell your doctor or pharmacist if you take, have recently taken or would take any other medicine. IPPROTON 40 mg powder for injection may interact with other medicines and some medicines may have an effect on IPPROTON 40 mg powder for injection.
You should not take IPPROTON 40 mg powder for injection if you are taking a medicine containing nelfinavir (used for HIV). You should tell your doctor or pharmacist if you are taking any of the following medicines :
• Ketoconazole, itraconazole, posaconazole or voriconazole (used in the treatment of fungal infections) ;
• Digoxin (used in the treatment of heart deseases);
• Diazepam (used in the treatment of anxiety, epilepsy or as muscle relaxant) ;
• Phenytoïn (used in epilepsy) ; if you are taking phenytoin, monitoring by your doctor is required at the start and at the end of the administration of IPPROTON 40 mg powder for injection ;
• Anti-coagulant medications for thinning blood such as warfarin or other anti-vitamin K ; monitoring by your doctor is required at the start and at the end of the administration of IPPROTON 40 mg powder for injection;
• Rifampicin (used to treat tuberculosis) ;
• Atazanavir (used to treat HIV infection) ;
• Tacrolimus (in case of organ transplant) ;
• St. John's wort (Hypericumperforatum) (used in the treatment of moderate depression) ;
• Cilostazol (used in the treatment of intermittent claudication) ;
• Saquinavir (used in the treatment of HIV infection) ;
• Clopidogrel (used to prevent blood clots (thrombus)) ;
• Erlotinib (used in the treatment of cancer) ;
• Methotrexate (medication used in high-dose chemotherapy for the treatment of cancer) - if you take a high dose of methotrexate, your doctor may temporarily stop your treatment of omeprazole.
If your doctor has prescribed you the following antibiotics: amoxicillin and clarithromycin with IPPROTON 40 mg, powder for injection to treat a Helicobacter Pylori ulcer, it's important to inform your doctor about all the medications you are taking.
If you are going to undergo medical examinations at the hospital, tell your doctor as you may need to stop the treatment for a short period.

IPPROTON 40 mg, powder for injection with food and drinks
Not Applicable.

Pregnancy and breast-feeding
Pregancy
If you are pregnant or like to be, tell your doctor before you take IPPROTON 40mg, powder for injection. Your doctor will decide if you can take IPPROTON 40 mg, powder for injection during this period.
Breast-feeding
Omeprazole is excreted into breast milk but it's unlikely that there's influence on your child at the taken therapeutic doses. Your doctor will tell you if you can take IPPROTON 40 mg, powder for injection during breast-feeding.

Driving and using machines
IPPROTON 40 mg powder for injection is not expected to affect the ability to drive and use machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If so, you must not drive or use machinery.

IPPROTON 40 mg, powder for injection contains sodium.

3. HOW TO TAKE IPPROTON 40 mg, powder for injection?

IPPROTON 40 mg, powder for injection may be administred to adults and elderly.
Experience is limited for use of IPPROTON 40 mg Powder for Intravenous Injection in children.

Dosage
IPPROTON 40 mg powder for injection will be given to you by a doctor who will decide the dose you need.
IPPROTON 40 mg powder for injection will be administered by infusion into one of your veins.

If you are given more IPPROTON 40 mg, Powder for Injection, than you should have taken :
If you think you have received too much IPPROTON 40 mg powder for injection, talk to your doctor immediately.

If you forgot to take IPPROTON 40 mg, powder for injection
Not Applicable.
If you stop taking IPPROTON 40 mg, powder for injection Not Applicable.

4. POSSIBLE SIDE EFFECT ?

Like any medicine, this medication can cause side effects, but they do not occur systematically in everyone.

If you notice the following side effects, these are rare but serious, stop taking IPPROTON 40 mg, powder for injection and talk to your doctor immediatly:
• Sudden onset of wheezing, swelling of the lips, tongue and throat or body, rash, loss of consciousness or difficulty swallowing (severe allergic reactions).
• 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 may be Stevens-Johnson syndrome or toxic epidermal necrolysis.
• Jaundice, dark urine and fatigue can be symptoms of liver problems.

Other side effects:
Common side effects (may affect 1 in 10 peolpe):
• headache.
• Effects on the stomach or intestine: diarrhea, stomach ache, constipation, flatulence, benign polyps in the stomach.
• Nausea, vomiting.
Uncommon side effects (may affect 1 in 100 people):
• Swelling of the feet and ankles.
• Sleep disorders (insomnia).
• Dizziness, tingling, drowsiness.
• Dizziness.
• Changes in blood test results which are controlling the functioning of your liver.
• Rash, hives and itching of the skin.
• General discomfort and lack of energy.
• Fracture of the hip, wrist or vertebrae.
Rare side effects (may affect 1 in 1000 people):
• Blood disorders such as a decrease in the number of white blood cells or platelets.
These effects can cause weakness, bruising or facilitate the occurrence of infections.
• Allergic reactions, sometimes very serious including swelling of the lips, tongue and throat, fever, wheezing.
• Decreased level of sodium in the blood. It can cause weakness, vomiting and cramps.
• Restlessness, confusion or depression.
• Taste disorders.
• Vision disorders, such as blurred vision.
• Wheezing or shortness of breath (bronchospasm).
• dry mouth.
• An inflammation of the inside of the mouth.
• Infection called "thrush" that can affect the bowel and it's caused by a fungus.
• Hepatic disorders including jaundice, may cause yellow-colored skin, dark urine and fatigue.
• Hair loss (alopecia).
• Rash on exposure to the sun.
• Joint pain (arthralgia) or muscle pain (myalgia).
• Severe kidney problems (interstitial nephritis).
• Increased sweat.
• Inflammation of the intestine (causing diarrhea).
Very rare side effects (may affect 1 in 10000 people):
• Modification in the number of blood cells including agranulocytosis(white cells deficit).
• Aggressiveness.
• Visual, sensory or auditory hallucinations.
• Severe liver problems leading to liver failure and inflammation of the brain.
• Sudden onset of severe rash, severe blistering or peeling of the skin that may be associated with severe fever and joint pain (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
• Muscle weakness.
• Breast swelling in men.
Not known frequency (the frequency can not be estimated from the available data)
• rash, potentially accompanied by joint pain
• If you have been taking IPPROTON for more than three months, it is possible that the level of magnesium in your blood is decreasing. Low levels of magnesium can lead to fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, rapid heartbeat.
If you have any of these symptoms, talk to your doctor immediately. A low level of magnesium can also cause a decrease in potassium or calcium levels in the blood. Your doctor may decide to have regular blood tests to monitor your magnesium levels.
Cases of irreversible visual impairment has been reported in isolated number of patients with severe impairment of general condition and who received intravenous omeprazole primarily in high doses but no causal relationship has been established.
IPPROTON 40 mg injection powder may in very rare cases affect the white blood cells leading to immune deficiency. You should consult your doctor as soon as possible if you have an infection with symptoms such as fever with a very large general fatigue, or fever with symptoms of local infection such as pain in the neck, throat, mouth, or difficulty passing urine. If you have these symptoms, a deficiency of white blood cells (agranulocytosis) can be eliminated by a blood test. In this case ; it's important to provide information about your medications.
Don't worry about the eventual side effects in this list, you may have none.

Reporting of side effects
If you get any side effect, talk to your doctor, pharmacist or nurse. This also applies to any side effect that is not mentioned in this leaflet. You can also report side effects directly through the national reporting system. By reporting side effects you can help provide more information on the safety of the medicine.

5. HOW TO STORE IPPROTON 40 mg, POWDER FOR INJECTION ?

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date stated on the vial and the box. The expiry date refers to the last day of that month.
Before opening : to be stored at a temperature not exceeding 25°C. Keep the vial in the outer packaging in order to protect it from light.
After reconstitution : The reconstituted solution should be used within 12 hours after reconstitution in sterile 0.9% sodium chloride solution and for 6 hours in 5% glucose solution.
However, from a microbiological point of view, the product should be used immediately unless reconstituted under 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 protect the environment.

6.CONTENT OF THE OUTER PACKAGING AND OTHER INFORMATION

What IPPROTON 40 mg, powder for injection
• The active substance is : Omeprazole (as omeprazole sodium).
Each vial contains 40 mg of omeprazole.
• the other ingredients are :
Disodium Edetate, Sodium Hydroxide.

What IPPROTON 40 mg, powder for injection looks like and content of the outer packaging
Powder in colorless glass vial of type I.

Marketing Authorization Holder and Manufacturer
LES LABORATOIRES MEDIS
Road of Tunisie - KM 7 - BP 206 - 8000 Nabeul - Tunisia
Tel : +216 72 23 50 06. Fax: +216 72 23 50 16.
E-mail : contact@labomedis.com

Supply and prescription Conditions :
List II

M.A.N:
IPPROTON 40mg, box of 10 vials : 923 327 1H
IPPROTON 40mg, box of 01 vial : 923 327 5

This leaflet was last revised in : 11/2019

The following information is intended for healthcare professionals only:
The entire content of each vial is to be dissolved in approximately 2 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.
Preparation
1. With a syringe draw 2 ml of infusion solution from the 100 ml infusion bottle or bag.
2. Add this volume to the vial with the freeze-dried omeprazole, mix thoroughly making sure all omeprazole is dissolved.
3. Draw the omeprazole solution back into the syringe.
4. Transfer the solution into the infusion bag or bottle.
5. Repeat steps 1-4 to make sure all omeprazole is transferred from the vial into the infusion bag or bottle.

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.

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This is a medicine
- A medicine is a product but not like any other product.
- A medicine is a product that affects your health.if it's not used properly : it can be health threatening.
- Strictly adhere to the prescription of you Doctor and the use instructions prescribed, follow your pharmacist advice.
- Your doctor and you pharmacist know the medicine, its use and side effect.
- Don't stop the use of the treatment on your own during the prescribed time.
- Don't retake, Don't increase the doses without doctor's advice.

Keep the medicines out of reach of children