Pantotaj®

Pantoprazole gastro-resistant Tablets / Capsules
Pantoprazole Powder For Solution For Injection
Pantoprazole Oral Suspension

Pantoprazole 40mg, powder for solution for injection
Pantoprazole
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 Pantoprazole 40mg Powder for Solution for Injection is and what it is used for

Pantoprazole 40mg powder for solution for injection is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in your stomach. It is used for treating acid-related diseases of the stomach and intestine. This preparation is injected into a vein and will only be given to you if your doctor thinks pantoprazole injections are more suitable for you at the moment than pantoprazole tablets. Tablets will replace your injections as soon as your doctor sees fit. Pantoprazole 40mg powder for solution for injection is used for treating:
• Reflux oesophagitis. An inflammation of your oesophagus (the tube which connects your throat to your stomach) accompanied by the regurgitation of
stomach acid.
• Stomach and duodenal ulcers
• Zollinger-Ellison syndrome and other conditions producing too much acid in your stomach.

2. What you need to know before you use Pantoprazole powder

Do not use Pantoprazole 40mg powder for solution for injection
• if you are allergic to pantoprazole or any of the other ingredients of this medicine (listed in section 6).
• if you are allergic to medicines containing other proton pump inhibitors. Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Pantoprazole powder
• if you have severe liver problems. Please tell you doctor if you ever had problems with your liver in the past. He will check your liver enzymes more frequently. In case of a rise of liver enzymes the treatment should be stopped.
• if you are taking a medicine containing atazanavir (for the treatment of HIV infection) at the same time as pantoprazole, ask your doctor for specific advice.
• if you have ever had a skin reaction after treatment with a medicine similar
to Pantoprazole powder that reduces stomach acid.
• if you are due to have a specific blood test (Chromogranin A). 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 Pantoprazole powder. Remember to also mention any other ill effects like pain in your joints.

Tell your doctor immediately if you notice any of the following symptoms:
• an unintentional weight loss
• repeated vomiting
• difficulty in swallowing
• vomiting blood
• you look pale and feel weak (anaemia)
• you notice blood in your stools
• severe and/or persistent diarrhoea, as pantoprazole has been associated with a small increase in infectious diarrhoea. Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole also alleviates the symptoms of cancer and could cause delay in diagnosing it. If you symptoms continue in spite of your treatment, further investigations will be considered.
Children and adolescents
These injections are not recommended for use in children.
Other medicines and Pantoprazole powder
Pantoprazole injections may influence the effectiveness of other medicines, so tell you doctor if you are taking:
• Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because pantoprazole may stop these and other medicines from working properly.
• Warfarin and phenprocoumon, which affect the thickening or thinning of the blood. You may need further checks.
• Atazanavir (used to treat HIV infection).
• Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Pantoprazole powder treatment.
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.
Pregnancy and breast-feeding There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for
advice before taking this medicine. If you are pregnant you should use this medicine only if your doctor considers the benefit for you is greater than the potential risk for your unborn child or baby. Driving and using machines If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines. Pantoprazole powder contains sodium. This medicinal product contains less than 1mmol of sodium (23mg) per dose, i.e. essentially "sodium-free".

3. How to use Pantoprazole powder

Your doctor or nurse will administer the daily dose to you as an injection into a vein over a period of 2-15 minutes.
The recommended dose is: For gastric ulcers, duodenal ulcers and reflux oesophagitis One vial (40mg pantoprazole) a day. For the long-term treatment of Zollinger- Ellison syndrome and other conditions in which too much stomach acid is produced.
Two vials (80mg pantoprazole) a day. Your doctor may later adjust the dose depending on the amount of stomach acid you produce. If you are prescribed more than two vials (80mg) a day, the injections will be in two equal doses. Your doctor may prescribe a temporary dose of more than four vials (160mg) a day. If your stomach acid level needs to be controlled rapidly, a starting dose of 160mg (four vials) should be enough to lower the amount of stomach acid sufficiently. Patients with liver problems , If you have severe liver problems the daily injection should be only 20mg (half a vial).
If you use more Pantoprazole 40mg powder for solution for injection than you should These doses are carefully checked by your nurse or doctor so an overdose is extremely unlikely. There are no known symptoms of overdose. 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 get any of the following side effects, tell you doctor immediately, or contact the casualty department at your nearest hospital:
• Serious allergic reactions (frequency rare; may affect up to 1 in 1,000 people): swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulty in breathing, allergic facial swelling (Quincke's oedema/angioedema), severe dizziness with very fast heartbeat and heavy sweating.
• Serious skin conditions (frequency not known; cannot be estimated from the available data): blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson Syndrome, Lyell Syndrome, Erythema multiforme) and sensitivity to light.
• Other serious conditions (frequency not known; cannot be estimated from the available data): yellowing of the skin or the whites of your eyes (severe damage to liver cells, jaundice) or fever, rash and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys which can also lead to kidney failure).
Other side effects are:
• Common (may affect up to 1 in 10 people): inflammation of the wall of the vein and blood clotting (thrombophlebitis) where the medicine is injected, benign polyps in the stomach.
• Uncommon (may affect up to 1 in 100 people) headache; dizziness; diarrhoea; feeling sick; vomiting; bloating and flatulence (wind); constipation; dry mouth; abdominal pain and discomfort; skin rash; exanthema, eruption; itching; feeling weak; exhausted or generally unwell; sleep disorders.
• Not known (frequency cannot be estimated from the available data) hallucination, confusion (especially in patients with a history of these symptoms); sensation of tingling, pins and needles (paraesthesia); muscle spasms due to electrolyte disturbances (changes in the salt levels in the body); rash, possibly with pain in the joints.
Side effects identified through blood tests:
, which may cause you to bleed or bruise more than normal; a reduction in white cells in your blood which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets.
• Not known (frequency cannot be estimated from the available data) Decreased sodium level in blood; Low levels of magnesium and potassium in the blood. Low levels of magnesium can also lead to a reduction of calcium levels in the blood. 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.

5.How to store Pantoprazole powder

Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and the vial after EXP.
The expiry date refers to the last day of the month.
Do not store above 25°C.
Keep the vial in the outer carton in order to protect from light.
After reconstitution, or reconstitution and dilution, chemical and physical in-use stability has been demonstrated for 12 hours at 25°C.
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.
Do not use this medicine if you notice that the visual appearance has changed (e.g. if cloudiness or precipitation is observed).
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. Contents of the pack and other information

What Pantoprazole 40mg powder
for solution for injection contains
• The active substance is pantoprazole. Each vial contains 40mg of pantoprazole (as sodium) IP
• The other ingredients are: - mannitol, - sodium citrate dihydrate - sodium hydroxide for pH adjustment
What Pantoprazole 40mg powder for solution for injection looks like and contents of the pack Pantoprazole 40mg powder for solution for injection is a white or almost white uniform porous cake.
It comes in packs of 1, 5, 10 and 20 glass vials.

Manufactured in India by:
TAJ PHARMACEUTICALS LTD.
Mumbai, India
Unit No. 214.Old Bake House,
Maharashtra chambers of Commerce Lane,
Fort, Mumbai - 400001
at :Sabarkantha, Gujarat - INDIA.
Code No.: PRINTED ON BOX.
WHO-cGMP & ISO 9001:2015 Certified Company

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.
This leaflet was last revised in March 2018.

Not all pack sizes may be marketed.

This leaflet was last revised in April 2018

The following information is intended for healthcare professionals only: A ready-to-use intravenous solution is prepared by injecting 10ml of sodium
chloride 9mg/ml (0.9%) solution for injection into the vial containing the lyophilised powder. The solution may either be administered directly or after mixing it with 100ml of sodium chloride 9mg/ml (0.9%) solution for injection or glucose 50mg/ml (5%) solution for injection. Glass or plastic containers should be used for dilution. Pantoprazole 40mg, powder for solution for injection should not be prepared or mixed with solvents other than those stated. In order to avoid risk of coring during needle insertion through the rubber stopper, a needle with an outside diameter of less than or equal to 0.8mm should be used during preparation of the solution. After reconstitution, or reconstitution and dilution, chemical and physical inuse stability has been demonstrated for 12 hours at 25°C. The reconstituted, or reconstituted and diluted medicinal product should not be refrigerated.
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. The medicine should be administered intravenously over 2 – 15 minutes. The content of the vial is for single intravenous use only. Any product that has remained in the container or the visual appearance of which has changed (e.g. if cloudiness or precipitation is observed) must be discarded.