PACKAGE LEAFLET: INFORMATION FOR THE USER

Pantoprazole Azevedos 40mg powder for solution for injection/infusion
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, or pharmacist or nurse.
- If you get any side effects talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pantoprazole Azevedos is and what it is used for

Pantoprazole Azevedos 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 administered into a vein and will only be given to you if your doctor thinks pantoprazole injections or infusions are more suitable for you at the moment than pantoprazole tablets. Tablets will replace your injections or infusions as soon as your doctor sees fit.

Pantoprazole Azevedos 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 the stomach.

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

Do not use Pantoprazole Azevedos
- If you are allergic (hypersensitive) to pantoprazole or any of the other ingredients of Pantoprazole Azevedos (see section 6).
- If you are allergic to medicines containing other proton pump inhibitors.

Warnings and precautions
- If you have severe liver problems. Please tell your doctor if you ever had problems with your liver in the past. He will check your liver enzymes more frequently. In the case of a rise of liver enzymes the treatment should be stopped.
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long-term treatment with pantoprazole. As with all acid reducing agents, pantoprazole may lead to a reduced absorption of vitamin B12.
- 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.
- People who take multiple daily doses of proton pump inhibitor medicines for a long period of time (a year or longer) may have an increased risk of fractures of the hip, wrist or spine. Talk to your doctor about your risk of bone fracture if you take Pantoprazole Azevedos.

- If you have low magnesium levels in your body. This problem can be serious. Low magnesium can happen in some people who take proton pump inhibitor medicine for at least 3 months. If low magnesium levels happen, it is usually after a year of treatment. You may or may not have symptoms of low magnesium.

Talk to your doctor before taking Pantoprazol Azevedos:
- if you have ever had a skin reaction after treatment with a medicine similar to Pantoprazol Azevedos 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 Pantoprazol Azevedos. 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 loss of weight
- vomiting, particularly if repeated
- difficulty in swallowing or pain when swallowing
- vomiting blood ; this may appear as dark coffee grounds in your vomit
- you look pale and feel weak (anaemia)
- you notice blood in your stools, which may be black or tarry in appearance
- chest pain
- stomach pain
- severe and/or persistent diarrhoea, as Pantoprazole Azevedos 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 your symptoms continue in spite of your treatment, further investigations will be considered.

Children and adolescents
Pantoprazole Azevedos is not recommended for use in children as it has not been proven to work in children below 18 years of age.

Other medicines and Pantoprazole Azevedos
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer) because Pantoprazole Azevedos 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 (used to treat rheumatoid arthritis, psoriasis and cancer) – if you are taking methotrexaate your doctor may temporarily stop your Pantoprazole Azevedos treatment because pantoprazole can increase levels of methotrexate in the blood.

In the case of combination therapy, the patient leaflets of the respective medicinal products should be observed.

Pregnancy, breast-feeding and fertility
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.
There are no adequate data from the use of pantoprazole in pregnant women. Excretion into human milk has been reported.

You should use this medicine, only if your doctor considers the benefit for you greater than the potencial 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 Azevedos contains less than 1 mmol sodium (23 mg) per vial, i.e. is essentially 'sodium-free'.

3. How to use Pantoprazole Azevedos

Your nurse or your doctor will administer the daily dose to you as an injection or infusion into a vein over a period of 2 - 15 minutes.

The recommended dose is:
Adults
For gastric ulcers, duodenal ulcers and reflux oesophagitis:
One vial (40 mg pantoprazole) once a day.

For the long-term treatment of Zollinger-Ellison syndrome and other conditions in which too much stomach acid is produced:
Two vials (80 mg 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 (80 mg) a day, the injections will be given in two equal doses. Your doctor may prescribe a temporary dose of more than four vials (160 mg) a day. If your stomach acid level needs to be controlled rapidly, a starting dose of 160 mg (four vials) should be enough to lower the amount of stomach acid sufficiently.

Patients with liver problems:
- If you suffer from severe liver problems, the daily injection/infusion should be only 20 mg (half a vial).

Use in children and adolescents
- Children (under 18 years). These injections/infusions are not recommended for use in children.

If you use more Pantoprazole Azevedos than you should
These doses are carefully checked by your nurse or your doctor so an overdose is extremely unlikely. There are no known symptoms of overdose.

If you have any further questions about the use of this medicine, ask your doctor, or 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 your doctor immediately, or contact the casualty department at your nearest hospital:
Rare: may affect up to 1 in 1,000 people:
- Serious allergic reactions: swelling of the tongue and/or throat, difficulty in swallowing, hives (nettle rash), difficulties in breathing, allergic facial swelling (Quincke's oedema / angioedema), severe dizziness with very fast heartbeat and heavy sweating.

Not known: frequency cannot be estimated from the available data

- Serious skin conditions: 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: yellowing of the skin or whites of the 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).

Other side effects are:

Common: may affect up to 1 in 10 people:
- benign polyps in the stomach, inflammation of the wall of the vein and blood clotting (thrombophlebitis) where the medicine is injected.

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. Taking proton pump inhibitor like pantoprazole, especially over 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 oncrease the risk of osteoporosis).

Rare: may affect up to 1 in 1,000 people:
- disturbances in vision such as blurred vision; hives; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities (peripheral oedema); allergic reactions; depression; breast enlargement in males; distortion or complete lack of sense of taste.

Very rare: may affect up to 1 in 10,000 people:
- disorientation.

Not known: frequency cannot be estimated from the available data
- hallucination, confusion (especially in patients with a history of these symptoms); decreased sodium level in blood; decreased magnesium level in blood; rash, possibly with pain in the joints; feeling of tingling, prickling, pins and needles, burning sensation or numbness; low levels of potassium which can cause muscle weackness, twitching or abnormal heart rhythm; muscle spams or cramps; low levels of calcium. If you are on Pantoprazole Azevedos 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, increase 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 (see section 2).

Side effects identified through blood tests:
- Uncommon: may affect up to 1 in 100 people:
- an increase in liver enzymes.

Rare: may affect up to 1 in 1,000 people:
- an increase in bilirubin; increased fat levels in blood; sharp drop in circulating granular white blood cells, associated with high fever.

Very rare: may affect up to 1 in 10,000 people:
- a reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets.

Reporting of side effects

If you get any side effect, talk to your doctor, or 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

5. How to store Pantoprazole Azevedos

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 that month.

Do not store above 25°C. Keep the vial in the outer carton in order to protect it from light.

The reconstituted solution of 40 mg/10 ml is stable for a period of 24 hours of initial puncture of stopper. Chemical and physical in-use stability has been demonstrated for 12 hours at 25ºC after dilution with sodium chloride 9 mg/ml (0.9%) solution and with glucose 50 mg/ml (5%) solution.
The diluted solutions with sodium chloride 9 mg/ml (0,9%) solution and with dextrose 50 mg/ml (5%) solution at concentrations of 80 and 160mg doses should be administered within the infusion time of 15 minutes .
From a microbiological point of view, the product should be used immediately.

Any product that has remained in the container must be discarded.
Do not use this medicine if you notice any particles are present in the reconstituted solution.

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 Pantoprazole Azevedos contains

- The active substance is pantoprazole. Each vial contains 40 mg of pantoprazole (as sodium sequihydrate).
- The other ingredients are: sodium hydroxide (for pH adjustment).

What Pantoprazole Azevedos looks like and contents of the pack

Pantoprazole Azevedos is a white to off-white powder for solution for injection/infusion. It comes in a 10 ml clear glass vial closed with an aluminium cap and grey rubber stopper containing 40 mg powder for solution for injection/infusion.
Pantoprazole Azevedos is available in the following pack sizes:

Pack with 1 vial.
Pack with 5 vials.
Pack with 10 vials.
Pack with 20 vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Laboratórios Azevedos – Indústria Farmacêutica, S.A.
Estrada Nacional 117-2 Alfragide, 2614-503 Amadora
Portugal

Manufacturer

Sofarimex – Indústria Química e Farmacêutica, Lda
Av. das Indústrias – Alto do Colaride; Agualva
2735-213 CACÉM
Portugal

This leaflet was last revised in 06/2018.

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

A ready-to-use solution is prepared by injecting 10 ml of sodium chloride 9 mg/ml (0.9 %) solution for injection into the vial containing the dry powder. This solution may either be administered directly or after mixing it with 100 ml sodium chloride 9 mg/ml (0.9 %) solution for injection or glucose 50 mg/ml (5 %) solution for injection. The appearance of the product after reconstitution is a clear brownish solution. Do not use if any particles are present in the reconstituted solution.

Pantoprazole Azevedos should not be prepared or mixed with solvents other than those stated.

The reconstituted solution of 40 mg/10 ml is stable for a period of 24 hours of initial puncture of stopper. Chemical and physical in-use stability has been demonstrated for 12 hours at 25ºC after dilution with sodium chloride 9 mg/ml (0.9%) solution and with glucose 50 mg/ml (5%) solution.
The diluted solutions with sodium chloride 9 mg/ml (0,9%) solution and with dextrose 50 mg/ml (5%) solution at concentrations of 80 and 160mg doses should be administered within the infusion time of 15 minutes .
From a microbiological point of view, the product should be used immediately.

The medicine should be administered intravenously over 2 - 15 minutes.

Any product that has remained in the container must be discarded.