PACKAGE LEAFLET

Package leaflet: Information for the user

Pantoprazole 40 mg powder for solution for injection

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.

What is in this leaflet

1. What Pantoprazole is and what it is used for

Pantoprazole 40 mg powder for solution for injection contains the active substance pantoprazole. Pantoprazole 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 is used for treating adults for:
- 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

Do not use Pantoprazole
- if you are allergic to pantoprazole or to 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:
- if you have severe liver problems. Please tell your doctor if you have ever had problems with your liver in the past. Your doctor will check your liver enzymes more frequently. In the case of a rise of liver enzymes the treatment should be stopped.
- if you are taking HIV protease inhibitors such as atazanavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.
- taking a proton pump inhibitor like pantoprazole, 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 (reduced bone density) or if you have been told that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- if you are on pantoprazole 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 or 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.
- if you have ever had a skin reaction after treatment with a medicine similar to pantoprazole that reduces stomach acid.
- 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. Remember to also mention any other ill-effects like pain in your joints.
- serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and erythema multiforme, have been reported in association with pantoprazole treatment. Stop using pantoprazole and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- if you are due to have a specific blood test (Chromogranin A).

Tell your doctor immediately, before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:
- an unintentional loss of weight
- vomiting, particularly if repeated
- vomiting blood; this may appear as dark coffee grounds in your vomit
- you notice blood in your stools; which may be black or tarry in appearance
- difficulty in swallowing or pain when swallowing
- you look pale and feel weak (anaemia)
- chest pain
- stomach pain
- severe and/or persistent diarrhoea, because this medicine 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.

This medicine may affect the way that your body absorbs vitamin B12, particularly if you need to take it for a long time. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B12:
- Extreme tiredness or lack of energy
- Pins and needles
- Sore or red tongue, mouth ulcers
- Muscle weakness
- Disturbed vision
- Problems with memory, confusion, depression

Children and adolescents
Pantoprazole 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
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This is because pantoprazole may influence the effectiveness of other medicines, so tell your 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
- medicines used to treat HIV-infection, such as atazanavir
- methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) - if you are taking methotrexate your doctor may temporarily stop your pantoprazole treatment because pantoprazole can increase levels of methotrexate in the blood
- fluvoxamine (used to treat depression and other psychiatric diseases) - if you are taking fluvoxamine your doctor may reduce the dose
- rifampicin (used to treat infections)
- St. John's Wort *(*Hypericum perforatum*)* (used to treat mild depression)
- talk to your doctor before taking pantoprazole if you are due to have a specific urine test (for THC; Tetrahydrocannabinol).

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.

You should use this medicine only if your doctor considers the benefit for you greater than the potential risk for your unborn child or baby.

Driving and using machines
Pantoprazole has no or negligible influence on the ability to drive and use machines.
If you experience side effects like dizziness or disturbed vision, you should not drive or operate machines.

Pantoprazole contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per maximum daily dose, that is to say essentially 'sodium- free'.

3. How to use Pantoprazole

Your nurse or your doctor will administer the daily dose to you as an injection 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) 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 should be only 20 mg (half a vial).

Use in children and adolescents
These injections are not recommended for use in children and adolescents under 18 years.

If you use more Pantoprazole 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 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 your doctor immediately, **or contact the casualty department at your nearest hospital:**

- **Serious allergic reactions (frequency rare:** may affect less than 1 in 1,000 people**):** 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.

- **Serious skin conditions (frequency not known:** frequency cannot be estimated from the available data**):** you may notice one or more of the following- blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals, or skin sensitivity/rash, particularly in areas of skin exposed to light/the sun. You may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

- **Other serious conditions (frequency not known:** frequency cannot be estimated from the available data**):** 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), possibly leading 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, fracture in the hip, wrist or spine.

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

- **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); feeling of tingling, prickling, pins and needles, burning sensation or numbness, rash, possibly with pain in the joints, inflammation in the large bowel, that causes persistent watery diarrhoea.

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, co-existing 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 level of sodium, magnesium, calcium or potassium in blood (see section 2).

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Pantoprazole

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 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 from light.

After the 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 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 to protect the environment.

6. Contents of the pack and other information

What Pantoprazole contains
The active substance is pantoprazole sodium sesquihydrate. Each vial contains 40 mg of pantoprazole (as sodium sesquihydrate).
The other ingredients are: mannitol and sodium phosphate dodecahydrate (for pH adjustment).

What Pantoprazole looks like and contents of the pack
Pantoprazole is a white to off-white porous cake or powder for solution for injection.

It comes in a 10 ml clear glass vial (type I) sealed with bromobutyl rubber stopper and an aluminium flip-off over seal, containing 40 mg powder for solution for injection.

Pantoprazole is available in the following pack sizes:

Pack sizes of 1, 5 and 10 vial(s).

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL
United Kingdom

Manufacturers[1]
Emcure Pharma UK Limited
Basepoint Business Centre, 110 Butterfield
Great Marlings, Luton LU2 8DL
United Kingdom.

MIAS Pharma Limited
Suite 2, Stafford House, Strand Road
Portmarnock, Co. Dublin, Ireland.

Tillomed Laboratories Limited
220 Butterfield, Great Marlings
Luton, LU2 8DL
United Kingdom.

This leaflet was last revised in 04/2024.

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. The appearance of the product after reconstitution is a colourless to yellowish clear liquid. 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 55 mg/ml (5 %) solution for injection. Glass or plastic containers should be used for dilution.

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

[1] Only the actual manufacturer is listed on the leaflet

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 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 whose visual appearance has changed (e.g. if cloudiness or precipitation is observed) must be discarded.