B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Pantoprazole 40 mg powder for solution for injection

pantoprazole sodium sesquihydrate

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.
- 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, 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 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
- 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 are given Pantoprazole

Do not use Pantoprazole
- 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 you are given Pantoprazole
- 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 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 SUN, 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 SUN. Remember to also mention any other ill-effects like pain in your joints.
- if you are due to have a specific blood test (Chromogranin A).

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, 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.

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. 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 (a type of rheumatism), psoriasis (a skin disease. The skin is red and dry with flakes), 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).

Pregnancy, breast-feeding and fertility

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 dose, that is to say essentially 'sodium- free'.

3. How Pantoprazole is given

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
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 (Stevens-Johnson-Syndrome, Lyell-Syndrome, erythema multiforme, subacute cutaneous lupus erythematosus, drug reaction with eosinophilia and systemic symptoms (DRESS), photosensitivity).

- **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 less than 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 less than 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 less than 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 less than 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 less than 1 in 100 people)**
  an increase in liver enzymes

- **Rare (may affect less than 1 in 1,000 people)**
  an increase in bilirubin; increased fats in the blood, sharp drop in circulating granular white blood cells, associated with high fever

- **Very rare (may affect less than 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.

- **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 and the vial after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

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, unless the method of opening and dilution precludes the risk of microbial contamination, the product should be used immediately.

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).

What Pantoprazole looks like and contents of the pack
Pantoprazole is a white to almost white powder for solution for injection. It comes in a 10 ml clear glass vial closed with a red aluminium seal and grey rubber stopper containing 40 mg powder for solution for injection.

Pantoprazole is available in the following pack sizes:
Packs with 1, 5, 10 and 50 vial(s).

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87
2132 JH Hoofddorp
The Netherlands

Manufacturer
Sun Pharmaceutical Industries Europe B.V.
Polarisavenue 87

2132 JH Hoofddorp
The Netherlands

S.C. Terapia S.A.
124 Fabricii Street
400632, Cluj-Napoca
Cluj County
Romania

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria:	Pantoprazol SUN 40 mg Pulver zur Herstellung einer Injektionslösung
Belgium:	Pantoprazol SUN 40 mg poeder voor oplossing voor injectie
	Pantoprazol SUN 40 mg poudre pour solution injectable
	Pantoprazol SUN 40 mg Pulver zur Herstellung einer Injektionslösung
Denmark:	Pantoprazol SUN
Germany:	Pantoprazol SUN 40 mg Pulver zur Herstellung einer Injektionslösung
Finland:	Pantoprazol SUN 40 mg injektiokuiva-aine, liuosta varten
France:	Pantoprazole SUN 40 mg poudre pour solution injectable
Italy:	Pantoprazolo SUN 40 mg polvere per soluzione iniettabile
The Netherlands:	Pantoprazol SUN 40 mg poeder voor oplossing voor injectie
Norway:	Pantoprazol SUN 40 mg pulver til injeksjonsvæske, oppløsning
Poland:	Pantoprazol SUN 40 mg proszek do sporządzania roztworu do wstrzykiwań
Romania:	Pantoprazol SUN 40 mg pulbere pentru soluţie injectabilă
Sweden:	Pantoprazol SUN 40 mg pulver till injektionsvätska, lösning
United Kingdom (Northern Ireland):	Pantoprazole 40 mg powder for solution for injection

This leaflet was last revised in 01/2023.

The following information is intended for 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 clear colorless solution, practically free from particles. 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.

After preparation, the solution must be used within 12 hours. 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 and would normally not be longer than 12 hours, at no more than 25 °C.

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.