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
2 What you need to know before you use Pantoprazole powder
3 How to use Pantoprazole powder
4 Possible side effects
5 How to store Pantoprazole powder
6 Contents of the pack and other information

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.

Your doctor has decided that pantoprazole 40mg is suitable for you 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)
- Gastritis which is an inflammation of the stomach lining
- 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).
- 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 your doctor if you ever had problems with your liver enzymes. If you tell your doctor your liver enzymes move more frequently. In case of a rare liver enzymes the treatment should be stopped.
- If you are taking a medicine containing alfaxarvar (for the treatment of HIV infection): at the same time as this medicine talk to your doctor for advice.
- If you have ever had a skin reaction after treatment with a medicine similar to Pantoprazole powder that reduces stomach acid.
- If your doctor has told you 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 using this medicine and seek medical advice. Remember to also mention any other ill-effects like pain in your joints.

Continued over page

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 (80mg 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 (160mg pantoprazole) a day.

Your doctor may later adjust the dose depending on the amount of stomach acid produced. In general, the daily dose is given 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 your liver enzyme problems the daily injection should be only 20mg (half a vial).

Tell your doctor immediately if you notice any of the following symptoms:

- an unintentional weight loss
- repeated vomiting
- difficulty in swallowing
- a smell of vomit
- you look pale and feel weak (anaemia)
- you notice blood in your stool.

If you develop any of these symptoms, or if you have any other symptoms which you think may be side effects, talk to your doctor or pharmacist.

4 Possible side effects

Pantoprazole has been associated with a small increase in rectal bleeding.

Your doctor may decide that you need some tests to see if you may have a particular disease because pantoprazole also alleviates the symptoms of a cancer and could cause delay in diagnosing it. If you get symptoms which you think may be side effects, tell your pharmacist or doctor.

Children and adolescents

These injections are not recommended for use in children.

Other medicines and Pantoprazole powder

Medicines other than pantoprazole may affect the effectiveness of other medicines, so tell your doctor if you are taking:

- Medicines such as losartan, irbesartan and piroxicam (used to treat fungal infections) or eritrelle (used for certain types of cancer) because pantoprazole may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thinning of your blood.
- All medicines that contain or are used to treat a hormone called 
  'Methotrexate' (used to treat leukaemia).
- Antibiotics (used to treat infection).
- Non-steroidal anti-inflammatory drugs (NSAIDs).
- Blood-thinning drugs such as aspirin or clopidogrel.

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 15mmol (0.5g) per dose, essentially "sodium-free".

5 How to store Pantoprazole powder

Pantoprazole 40mg powder for solution for injection contains:

• active ingredient: 40mg pantoprazole
• inactive ingredients: sodium hydroxide (use for adjusting the pH of the preparation), potassium chloride, hydroxypropyl methylcellulose, sodium metabisulfite (preservative) and mannitol (injection diluent).

The preparation is stored in a blister pack and protected from light.

The blister pack contains one vial of 80mg pantoprazole.

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Pantoprazole 40mg/15ml Powder for Solution for Injection 1 Vial PIL - UK

Colours

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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.

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 a doctor immediately, or contact the casualty department at your nearest hospital:

- Serious allergic reactions (frequency rarely; may affect up to 1 in 1,000 people); swelling of the tongue or throat, difficulty in swallowing, breathing difficulties (anaphylactic reaction), difficulty in breathing, allergic facial swelling (Quincke’s oedema/angioedema), severe dizziness with very fast heartbeat and faintness.

- Serious skin conditions (frequency not known; cannot be estimated from the available data): blistering of the skin and the whites of your eyes (severe damage to liver cells, jaundice); fever, rash and enlarged kidneys sometimes with painful urination and 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); nose/eye/ mouth/throat/thigh/neck pain; diarrhea; dizziness, feeling sick, vomiting, bloating and fullness (nausea); constipation; dry mouth; abdominal pain and diarrhoea; skin rash; nausea; injection; itching; feeling weak; exhaustion or generally unwell; sleep disorders.

- Rare (may affect up to 1 in 100 people); infection or complete lack of the sense of smell; heavy weight, blurred vision, lightheadedness; smell, taste; pain in the joints, muscle pain; weight change; mixed body temperature; sweating of the extremities (peripheral oedema); allergic reactions; depression; bruising, enlargement in muscles.

- Very rare (may affect up to 1 in 10,000 people)

- Not known (frequency cannot be estimated from the available data): hallucinations, confusion (especially in patients with a history of these symptoms); sensation of tingling, pins and needles (paraesthesia); muscle spasm due to electrolyte disturbances (changes in the electrolyte levels in the body); rash, possibly with burns in the joints.

Side effects identified through blood tests:

- Uncommon (may affect up to 1 in 100 people) increase in liver enzymes.

- Rare (may affect up to 1 in 1,000 people) increase in bilirubin; increased rate of liver function tests (transaminases, alkaline phosphatase).

- Very rare (may affect up to 1 in 10,000 people) increase in other liver enzymes; increase in the number of blood cells: proteins, which may cause skin or brain more than normal; a reduction in white cells in your blood which may lead to more frequent infections; constipation; abnormal reduction in the number of red and white blood cells, which can lead to anaemia.

- Other side effects cannot be estimated from the available data:

Decreased sodium level in blood; Low calcium level; high levels of magnesium and potassium in the blood; Low levels of magnesium and potassium in the blood; lead to a reduction of calcium levels in the blood; lead to electrolyte disturbances (changes in the electrolyte levels in the body); sodium citrate dihydrate; sodium sesquihydrate.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can report side effects directly by the Yellow Card Scheme at: www.yellowcard.gov.uk.

By reporting side effects you can help provide more information on the safety of this medicine.

Contradiction of use:

BBBA0559

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 21°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and use by dates 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 medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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 sesquihydrate). The following other ingredients are used:

- Sodium chloride 9mg/ml (0.9%) solution for injection to maintain isotonicity of the solution.

- Glucose 50mg/ml (0.9%) solution for injection.

- Other ingredients are:

- mannitol
- sodium citrate dihydrate
- sodium hydroxide for pH adjustment.

Pantoprazole 40mg powder for solution for injection looks like and contents of the pack

Pantoprazole 40mg powder for solution for injection is available as a white to almost white uniform porous cake.

It comes in packs of 1, 5, 10 and 20 glass vials.

Not all packs may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Nerviano, 20802 Alcalá de Henares (Madrid)

It was last revised in April 2017.