

### 1.3.2 PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

**S4**

**ASPEN PANTOPRAZOLE IV 40 mg/ 2 ml powder for solution for injection**

**Pantoprazole**

**Contains sugar: Mannitol 200 mg**

**Read all of this leaflet carefully before ASPEN PANTOPRAZOLE IV is administered to you**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ASPEN PANTOPRAZOLE IV has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### **What is in this leaflet**

1. What ASPEN PANTOPRAZOLE IV is and what it is used for
2. What you need to know before ASPEN PANTOPRAZOLE IV is administered to you
3. How ASPEN PANTOPRAZOLE IV will be administered to you
4. Possible side effects
5. How to store ASPEN PANTOPRAZOLE IV
6. Contents of the pack and other information.

## 1. What ASPEN PANTOPRAZOLE IV is and what it is used for

ASPEN PANTOPRAZOLE IV belongs to a group of medicines called proton pump inhibitors, i.e. it inhibits the enzyme which is responsible for gastric acid secretion in the cells of the stomach.

ASPEN PANTOPRAZOLE IV is used for the short-term treatment of duodenal ulcer (ulcer of the small intestine), stomach ulcer and reflux oesophagitis (inflammation of the gullet, caused by acid reflux). ASPEN PANTOPRAZOLE IV is used for intravenous administration in patients who cannot take their medicine by mouth (swallow). ASPEN PANTOPRAZOLE IV is used for the treatment of Zollinger-Ellison Syndrome (a rare disorder in which there is excessive secretion of gastric juice).

## 2. What you need to know before ASPEN PANTOPRAZOLE IV is administered to you

### ASPEN PANTOPRAZOLE IV should not be administered to you:

- if you have previously had an allergic reaction to pantoprazole or are allergic to any of the ingredients of ASPEN PANTOPRAZOLE IV.
- if your liver does not work properly (and this has been described by your doctor as 'severe').
- safety and efficacy in children have not been established.
- if you are taking a medicine containing atazanavir and nelfinavir (for the treatment of HIV-infection).

If you are unsure about this ask your doctor.

### Warnings and precautions

Take special care with ASPEN PANTOPRAZOLE IV:

- ASPEN PANTOPRAZOLE IV is only given intravenously. Your doctor or nurse will

administer the medicine.

- ASPEN PANTOPRAZOLE IV can cause an increased risk of kidney disease leading to kidney failure. This is called tubulointerstitial nephritis and you may have increased urine output, blood in your urine or dark urine, changes in mental status, such as drowsiness or confusion, swelling of any area of your body.
- If you have severe liver problems.
- If you experience unintentional loss of weight, repeated vomiting, difficulty swallowing, vomiting of blood, if you look pale and/or feel weak (anaemia) or if you notice blood in your stool or your stool appears black. Your doctor may decide that you need some tests to rule out malignant disease because pantoprazole in ASPEN PANTOPRAZOLE IV 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.
- If you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis). Receiving a proton pump inhibitor like ASPEN PANTOPRAZOLE IV especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine.
- If you have been receiving acid blocking medicines such as ASPEN PANTOPRAZOLE IV for longer than 3 years as it may lead to poor absorption of cyanocobalamin.
- If you are on ASPEN PANTOPRAZOLE IV for more than three months it is possible that the level of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, 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 experience severe fatigue, joint pain, joint swelling, headaches, a rash on the cheeks and nose, which is called a “butterfly rash”, hair loss, fingers turning white or blue and tingling when cold. These may be a sign of Systemic Lupus Erythematosus which is an autoimmune disease which occurs when the immune system attacks the body because it may confuse it for something foreign.
- If you experience watery stools, abdominal pain and fever whilst receiving ASPEN PANTOPRAZOLE IV. This may be a sign of *Clostridium difficile* associated diarrhoea (CDAD). You should seek immediate help from a healthcare provider.

### **Other medicines and ASPEN PANTOPRAZOLE IV**

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

ASPEN PANTOPRAZOLE IV can affect the absorption of medicines such as ketoconazole, itraconazole, posaconazole (used to treat fungal infections) and erlotinib (used to treat certain types of cancers) and must not be taken together with atazanavir or nelfinavir (for the treatment of HIV infection) as it can reduce the amount absorbed.

Your response to warfarin may be affected, therefore your blood should be monitored when you start or stop receiving ASPEN PANTOPRAZOLE IV or if you receive it irregularly.

ASPEN PANTOPRAZOLE IV can affect the concentration levels of medicines such as diazepam (used to treat anxiety, panic attacks and seizures), phenytoin (used to treat seizures), digoxin (used to treat certain types of heart disease), tacrolimus (used in organ transplants), clopidogrel (used to prevent blood clots) and mycophenolate mofetil (used to prevent organ transplant rejection).

ASPEN PANTOPRAZOLE IV can affect the concentration levels of methotrexate (used for the treatment of e.g. certain cancers, psoriasis, arthritis) – if you are receiving a high dose of methotrexate, your doctor may temporarily stop your ASPEN PANTOPRAZOLE IV treatment.

### **Pregnancy, breastfeeding and fertility**

Safety during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

### **Driving and using machines**

ASPEN PANTOPRAZOLE IV has moderate influence on the ability to drive and use machines.

It is not always possible to predict to what extent ASPEN PANTOPRAZOLE IV may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ASPEN PANTOPRAZOLE IV affects you (see section 4).

### **ASPEN PANTOPRAZOLE IV contains mannitol**

ASPEN PANTOPRAZOLE IV contains mannitol. If you have been told that you have an intolerance to some sugars, you should not be administered ASPEN PANTOPRAZOLE IV.

### **3. How ASPEN PANTOPRAZOLE IV will be administered to you**

Do not share medicines prescribed for you with any other person.

ASPEN PANTOPRAZOLE IV will be prepared by your doctor or nurse by dissolving it in the prescribed solvent. It is given by a single injection. Your doctor will determine the correct dosage for your condition.

The usual dose that is recommended is one vial (40 mg) per day.

ASPEN PANTOPRAZOLE IV is indicated for intravenous administration in patients who cannot be treated orally (by mouth).

ASPEN PANTOPRAZOLE IV may be used for up to 7 days. Treatment should be replaced with the same oral dose (taken by mouth) as soon as you are able to take medicine by mouth (swallow tablets).

#### **Duodenal ulcer (Ulcer of the small intestine)**

The recommended dose is 40 mg pantoprazole daily. The total treatment should be 2 to 4 weeks.

#### **Gastric ulcer (Stomach ulcer)**

The recommended dose is 40 mg pantoprazole once daily for 4 to 8 weeks.

#### **Reflux oesophagitis (Inflammation of gullet caused acid reflux)**

The recommended dose is 40 mg pantoprazole once daily for 4 to 8 weeks.

#### **Zollinger-Ellison syndrome**

For management of Zollinger-Ellison syndrome, you may receive up to 2 vials per day, given twice daily. Depending on your progress, the dosage can be adapted upwards or downwards as needed.

### **Elderly patients**

No dosage adjustment is needed in the elderly.

Your doctor will tell you how long your treatment with ASPEN PANTOPRAZOLE IV will last.

If you have the impression that the effect of ASPEN PANTOPRAZOLE IV is too strong or too weak, tell your doctor or pharmacist.

### **If you are given more ASPEN PANTOPRAZOLE IV than you should**

Since a healthcare provider will administer ASPEN PANTOPRAZOLE IV, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

### **If you forget to take ASPEN PANTOPRAZOLE IV**

Since a healthcare provider will administer ASPEN PANTOPRAZOLE IV, it is unlikely that the dose will be missed.

## **4. Possible side effects**

ASPEN PANTOPRAZOLE IV can have side effects.

Not all side effects reported for ASPEN PANTOPRAZOLE IV are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ASPEN PANTOPRAZOLE IV, please consult your healthcare provider for advice.

If any of the following happens, stop receiving ASPEN PANTOPRAZOLE IV and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- erythema multiforme (bull's eye-like lesion on skin),
- serious skin reactions, including shedding of scaly dead skin, extremely serious allergic skin reactions, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) and toxic skin degeneration.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ASPEN PANTOPRAZOLE IV. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- If you lose a lot of weight for no reason and have problems swallowing,
- if you get stomach pain or indigestion,
- jaundice (yellow eyes or skin),
- if you begin to vomit food or blood,
- if you pass black stools (blood-stained faeces),
- if you have watery stools,
- fatigue, painful muscle spasm, confusion, fits, dizziness and life-threatening irregular heart beat; these are symptoms of hypomagnesaemia (low magnesium levels),

- fracture of the hip, wrist or spine,
- painful urination and low back pain as these may be symptoms of kidney problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- Headache,
- constipation or flatulence.

*Less frequent side effects:*

- Trouble falling asleep or staying asleep through the night,
- fatigue,
- dizziness,
- disturbances in vision (blurred vision),
- sensation of tingling, burning, pricking, or numbness on your skin,
- confusion, excitement, restlessness, drowsiness,
- seeing, feeling or hearing things that are not there (hallucinations),
- hair loss,
- taste disturbance,
- the inability to achieve or sustain an erection,
- breast development in males,
- increased sweating,
- feeling of general discomfort or uneasiness,
- ringing in the ears,
- nausea and vomiting,
- pain in the joints and muscles,

- blood problems such as a reduced number of white cells (leukopenia) or platelets (thrombocytopenia) or a reduced number of white and red cells as well as platelets in the blood (pancytopenia). This can cause weakness, bruising or make infections more likely,
- changes in blood count including, agranulocytosis (lack of white blood cells),
- increased liver enzymes,
- increase in body temperature,
- weight changes,
- low levels of sodium, calcium and potassium in the blood,
- feeling agitated, confused or depressed,
- aggression,
- taste changes,
- spinning feeling (vertigo),
- dry mouth,
- skin rash on exposure to sunshine,
- wheezy or short of breath,
- inflammation of the inside of the mouth,
- injection site discomfort,
- kidney failure, (interstitial nephritis).

*Side effects with an unknown frequency:*

- tiny gastric polyps which may present as epigastric pain, nausea, vomiting and weight loss,
- anterior ischemic optic neuropathy which may present as visual loss, malaise, headache, scalp tenderness, jaw pain on mastication, generalised muscle aches and swelling.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA**: via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

### **Aspen Pharmacare:**

**E-mail:** [Drugsafety@aspenpharma.com](mailto:Drugsafety@aspenpharma.com)

**Tel:** 0800 118 088

By reporting side effects, you can help provide more information on the safety of ASPEN PANTOPRAZOLE IV.

### **5. How to store ASPEN PANTOPRAZOLE IV**

Store all medicines out of reach of children.

Store in a cool dry place at or below 25 °C.

Protect from light.

Keep in original packaging until required for use.

The reconstituted solution must be used immediately after preparation and any remaining solution must be appropriately disposed of.

Do not use after the expiry date stated on the label.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

**What ASPEN PANTOPRAZOLE IV contains**

The active substance is 40 mg of pantoprazole per 10 ml vial.

The other ingredients are mannitol, water for injection

Contains sugar: Mannitol 200 mg

**What ASPEN PANTOPRAZOLE IV looks like and contents of the pack**

White freeze dried powder.

The product is packed in a clear 10 ml amber Type I glass vial, with a grey bromobutyl rubber stopper and a purple aluminium cap.

**Holder of Certificate of Registration**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**Hotline:** 0800 122 912

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**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and Patient Information Leaflets:**



<https://www.sahpra.org.za/pi-pil-repository/>

**Aspen Pharmacare:**

**E-mail:** Medinfo@aspenpharma.com

**Tel:** 0800 118 088

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