

### 1.3.2 PATIENT INFORMATION LEAFLET

#### SCHEDULING STATUS

**S4**

#### **ASPEN PANTOPRAZOLE 20 mg enteric-coated tablets**

**Pantoprazole**

**Contains sugar: Mannitol 53,08 mg**

#### **ASPEN PANTOPRAZOLE 40 mg enteric-coated tablets**

**Pantoprazole**

**Contains sugar: Mannitol 106,17 mg**

#### **Read all of this leaflet carefully before you start taking ASPEN PANTOPRAZOLE**

- 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 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 is and what it is used for
2. What you need to know before you take ASPEN PANTOPRAZOLE
3. How to take ASPEN PANTOPRAZOLE
4. Possible side effects
5. How to store ASPEN PANTOPRAZOLE

## 6. Contents of the pack and other information

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

ASPEN PANTOPRAZOLE is used to treat certain conditions in which there is too much acid in the stomach.

It is used to treat ulcers in the small intestine and stomach, and gastro-oesophageal reflux disease (GERD), a condition in which the acid in the stomach washes back up into the oesophagus.

ASPEN PANTOPRAZOLE is also used for the treatment of Zollinger-Ellison Syndrome (a rare disorder in which there is excessive secretion of gastric juice).

ASPEN PANTOPRAZOLE works by decreasing the amount of acid produced by the stomach.

### 2. What you need to know before you take ASPEN PANTOPRAZOLE

#### **Do not take ASPEN PANTOPRAZOLE:**

- If you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of ASPEN PANTOPRAZOLE (listed in section 6).
- If you are pregnant or breast feeding your baby.
- If you have severely impaired liver function.
- If you are taking a medicine containing atazanavir or nelfinavir (for the treatment of HIV-infection).

Safety and efficacy in children have not been established.

#### **Warnings and precautions**

Take special care with ASPEN PANTOPRAZOLE:

- ASPEN PANTOPRAZOLE 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 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 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 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 for longer than 3 years it may lead to poor absorption of cyanocobalamin.
- If you are on ASPEN PANTOPRAZOLE 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 as it may confuse it for something foreign.
- If you experience watery stools, abdominal pain and fever whilst receiving ASPEN PANTOPRAZOLE. 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**

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

Tell your doctor if you are taking any of the following medicines:

ASPEN PANTOPRAZOLE 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 or if you receive it irregularly.

ASPEN PANTOPRAZOLE 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 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 treatment.

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

Safety in pregnancy and during lactation 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 has moderate influence on the ability to drive and use machines.

It is not always possible to predict to what extent ASPEN PANTOPRAZOLE 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 affects you (see section 4).

### **ASPEN PANTOPRAZOLE contains mannitol**

ASPEN PANTOPRAZOLE contains mannitol which may have an effect on the control of your blood sugar if you have diabetes mellitus.

ASPEN PANTOPRAZOLE may have a mild laxative effect.

## **3. How to take ASPEN PANTOPRAZOLE**

Always take ASPEN PANTOPRAZOLE exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended once daily dose of ASPEN PANTOPRAZOLE should be taken in the morning.

ASPEN PANTOPRAZOLE should be swallowed whole with a little water either before or during breakfast.

Do not crush, break, or chew the tablet.

Do not stop taking this medicine without checking with your doctor first.

Take this medicine for the full time of treatment even if you begin to feel better.

**Do not share medicines prescribed for you with others.**

Your doctor will decide on the correct dose of ASPEN PANTOPRAZOLE for you depending on which condition is being treated.

**Small intestine ulcer:** Take one 40 mg tablet once daily for 2 to 4 weeks.

**Stomach ulcer and reflux oesophagitis:** Take one 40 mg tablet once daily for 4 to 8 weeks.

**Excessive secretion of gastric juice:** Take two 40 mg tablets to start. Your doctor will tell you if you need to take more or less ASPEN PANTOPRAZOLE.

**Gastro-oesophageal reflux disease:** Take one 20 mg tablet per day for 4 weeks. Your doctor will tell you if you must take it for another 4 weeks.

**Long term management and prevention of relapse in gastro-oesophageal reflux disease:** Take one 20 mg tablet per day and increase to one 40 mg tablet per day (or two 20 mg tablets per day) if a relapse occurs. After healing of the relapse, the dose can be reduced to one 20 mg tablet per day.

Experience with long term treatment is limited.

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

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

#### **If you take more ASPEN PANTOPRAZOLE than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

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

If you have missed a dose of ASPEN PANTOPRAZOLE, take the dose that you have missed as soon as you remember. However if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

#### **4. Possible side effects**

ASPEN PANTOPRAZOLE can have side effects.

Not all side effects reported for ASPEN PANTOPRAZOLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ASPEN PANTOPRAZOLE, please consult your healthcare provider for advice.

If any of the following happens, stop taking ASPEN PANTOPRAZOLE 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).

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

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, magnesium, 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).

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.

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

Store all medicines out of reach of children.

Store at or below 25 °C.

Protect from light.

Keep in a well closed container.

Keep in original packaging until required for use.

Do not store in a bathroom.

Keep the blister strip in the box until required for use.

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

Return all unused medicine to your pharmacist.

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 contains**

Each enteric-coated tablet of ASPEN PANTOPRAZOLE 20 contains 20 mg of pantoprazole as pantoprazole sodium sesquihydrate.

Each enteric-coated tablet of ASPEN PANTOPRAZOLE 40 contains 40 mg of pantoprazole as pantoprazole sodium sesquihydrate.

The other ingredients are:

Calcium stearate, hypromellose, macrogol, mannitol, methacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, polyethylene glycol, propylene glycol, sodium carbonate anhydrous, sodium lauryl sulphate, sodium starch glycolate, talc, titanium dioxide, yellow iron oxide.

ASPEN PANTOPRAZOLE 20:

Contains sugar: Mannitol 53,08 mg

ASPEN PANTOPRAZOLE 40:

Contains sugar: Mannitol 106,17 mg

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

ASPEN PANTOPRAZOLE 20 are light yellow, oval, normal biconvex enteric-coated tablets.

ASPEN PANTOPRAZOLE 40 are dark yellow, oval, normal biconvex enteric-coated tablets.

ASPEN PANTOPRAZOLE 20

28, 30 or 100 enteric-coated tablets are packed in a white, round HDPE container with threaded neck with a white, round PP tamper-evident screw cap with three break-points on the ring and integrated desiccant and a leaflet.

28, 30 or 100 enteric-coated tablets are packed in an aluminium push through foil and sealed with an aluminium backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

#### ASPEN PANTOPRAZOLE 40

14, 15, 30 or 50 enteric-coated tablets are packed in a white, round HDPE container with threaded neck with a white, round PP tamper-evident screw cap with three break-points on the ring and integrated desiccant and a leaflet.

14, 15, 30 or 50 tablets are packed in an aluminium push through foil and sealed with an aluminium backing. The blister strips are packed into an outer cardboard carton together with a leaflet.

Not all packs or pack sizes may be marketed.

#### **HOLDER OF CERTIFICATE OF REGISTRATION**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**Hotline:** 0800 122 912

#### **This leaflet was last revised in:**

12 February 2024

#### **Registration number**

ASPEN PANTOPRAZOLE 20: 43/11.4.3/0545



ASPEN PANTOPRAZOLE 40: 43/11.4.3/0546

**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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