Approved Patient Information Leaflet for Medicines for Human Use:

PAZIPEP OTC

SCHEDULING STATUS: S2

PAZIPEP OTC enteric-coated tablet

Pantoprazole sodium sesquihydrate

Contains sugar (mannitol).

Each PAZIPEP OTC enteric-coated tablet contains 37,5 mg mannitol.

Contains less than 1 mmol sodium per dose.

Each 20 mg gastro-resistant tablet contains 7,998 mg (0,348 mmol) sodium, that is to say essentially 'sodium-free'.

Read all of this leaflet carefully before you start taking PAZIPEP OTC

- Keep this leaflet. You may need to read it again.
- Do not share PAZIPEP OTC with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What PAZIPEP OTC is and what it is used for
2. What you need to know before you take PAZIPEP OTC
3. How to take PAZIPEP OTC
4. Possible side effects
5. How to store PAZIPEP OTC
6. Contents of the pack and other information

1. What PAZIPEP OTC is and what it is used for

PAZIPEP OTC is a selective “proton pump inhibitor”, a medicine which reduces the amount of acid produced in your stomach.

PAZIPEP OTC is used (for a maximum of 14 days) for the short-term relief of heartburn and to treat conditions where the stomach produces too much acid (hyperacidity).

2. What you need to know before you take PAZIPEP OTC

Do not take PAZIPEP OTC:

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PAZIPEP OTC (listed in section 6)
- if you have serious liver problems
- if you are pregnant or breastfeeding your baby (see section 2, Pregnancy and breastfeeding)
- if you are taking medicines for HIV known as atazanavir or nelfinavir (antiretrovirals). These medicines may not work as well against your HIV infection if you take them with PAZIPEP OTC
- PAZIPEP OTC must not be given to children as is not known if it is safe and effective for them.

Warnings and precautions

Tell your doctor or healthcare professional before

PAZIPEP OTC:

Take special care with PAZIPEP OTC

- If you have severe liver problems or if you have ever had problems with your liver in the past. He will check your liver enzymes more frequently, especially when you are taking PAZIPEP OTC as a long-term treatment. In the case of a rise of liver enzymes the treatment should be stopped.

- If you have reduced body stores or risk factors for reduced vitamin B12 and receive pantoprazole long-term treatment, as pantoprazole may lead to a reduced absorption of vitamin B12.
- If you develop signs and symptoms of kidney problems such as blood in the urine, fever, changes in your normal urine volume, mental status changes (drowsiness, confusion, coma), nausea, vomiting, rash, swelling of any area of body and weight gain (from retaining fluid), call your doctor immediately PAZIPEP OTC can cause serious kidney problems such as acute interstitial nephritis, kidney injury and/or chronic renal failure. Your doctor will stop treatment with PAZIPEP OTC if he suspects you are experiencing kidney problems.
- If you are taking HIV protease inhibitors such as (for the treatment of HI- infection) at the same time as pantoprazole, ask your doctor for specific advice.
- If you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis. 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.
- If you need to take medicines called non-steroidal anti-inflammatory drugs (NSAIDs) continuously and receive PAZIPEP OTC
- PAZIPEP OTC as you have an increased risk of developing stomach and intestinal complications. Any increased risk will be assessed by your doctor according to your own personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or of stomach or intestinal bleeding.
- If you are on PAZIPEP OTC 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, 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 that reduces stomach acid such as PAZIPEP OTC.
- If you get a rash on your skin, especially in areas exposed to the sun, you may need to stop your treatment with PAZIPEP OTC. 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).
- If you have been taking continuously, for 2 weeks or longer, medicine for heartburn and/or indigestion, please consult your doctor.

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

- 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
- chest pain
- stomach pain
- you look pale and feel weak (anaemia)
- severe and/or persistent diarrhoea, as PAZIPEP OTC 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.

If you take PAZIPEP OTC on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Children and adolescents

PAZIPEP OTC must not be given to children as it is unknown if it is safe and effective for them (see "Do not take PAZIPEP OTC).

Other medicines and PAZIPEP OTC

Always tell your healthcare provider if you are taking any other medicine. This includes all complementary or traditional medicines.

PAZIPEP OTC may influence the effectiveness of other medicines

PAZIPEP OTC *may weaken the effect of the following medicines*

- Clopidogrel (an antiplatelet medicine that prevents platelets (a type of blood cell) from sticking together and forming a dangerous blood clot). You may have an increased risk of getting blood clots.
- Medicines such as ketoconazole, itraconazole and posaconazole (used to treat fungal infections) or erlotinib (used for certain types of cancer).
- Atazanavir and nelfinavir (used to treat HIV infection) – the blood levels may be decreased when taken together with PAZIPEP OTC and may cause the HIV to become resistant to this HIV medicine and cause it to stop working effectively. You must not take PAZIPEP OTC with atazanavir and nelfinavir (see section 2, Do not take PAZIPEP OTC
- Mycophenolate mofetil (used in combination with other medicines to keep your body from attacking and rejecting a transplanted organ, they belong to a class of medications called immunosuppressants) – pantoprazole may reduce exposure to the active metabolite, mycophenolic acid and cause the transplanted organ to be rejected.

PAZIPEP OTC *may strengthen the effect of the following medicines*

- Warfarin and phenprocoumon (used to thin the blood), this may lead to excessive bleeding. Your doctor may need to take regular blood tests to check how well your blood can clot.
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your PAZIPEP OTC treatment because pantoprazole can increase levels of methotrexate in the blood.
- Tacrolimus (used in combination with other medicines to keep your body from attacking and rejecting a transplanted organ, it belongs to a class of medications called immunosuppressants) – pantoprazole may increase blood levels of tacrolimus and lead to increased side effects and toxicity from this medicine, such as tremors, headaches and acute kidney failure.
- Digoxin for heart problems - PAZIPEP OTC may result in increased levels of digoxin in your blood with worsening of its unwanted effects.
- Diazepam (to calm you), and/or phenytoin (for epilepsy) - your doctor may want to decrease your doses.

Other medicines may influence the effectiveness PAZIPEP OTC

The following medicines may increase the blood levels of pantoprazole and strengthen the effect of* PAZIPEP OTC *or lead to more unwanted side effects

- Fluvoxamine (used to treat depression and other psychiatric diseases) – if you are taking fluvoxamine your doctor may reduce the dose of PAZIPEP OTC.
- Voriconazole (used to treat fungal infections) – if you are taking voriconazole your doctor may reduce the dose of PAZIPEP OTC.

***The following medicines may decrease the blood levels of pantoprazole and weaken the effect of* PAZIPEP OTC**

- Rifampicin (used to treat bacterial infections such as tuberculosis).

- St John’s wort (*Hypericum perforatum*) (a complementary medicine used to treat mild depression).

PAZIPEP OTC with food, drink and alcohol

PAZIPEP OTC may be taken either before or during breakfast without chewing or breaking them, swallow them whole with some water.

Pregnancy, breastfeeding and fertility

Do not take PAZIPEP OTC tablets if you are pregnant or breastfeeding your baby (see section 2 “Do not take PAZIPEP OTC

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.
Safety in pregnancy and during breastfeeding is unknown.

Driving and using machines

Pantoprazole does not adversely affect the ability to drive or use machines, however, adverse drug reactions such as dizziness and visual disturbances may occur. If affected, you should not drive or operate machines.

Excipient sodium

PAZIPEP OTC contains less than 1 mmol sodium per dose.

Each 20 mg gastro-resistant tablet contains 7,998 mg (0,348 mmol) sodium, that is to say essentially 'sodium-free'.

3. How to take PAZIPEP OTC

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

Always take PAZIPEP OTC exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one PAZIPEP OTC per day, for a maximum period of 14 days. If your symptoms do not improve after 14 days of continuous treatment, please consult your doctor as further investigation is recommended.

You should not take more than three 14-day courses of PAZIPEP OTC in a 12-month period without consulting your doctor.

The use of PAZIPEP OTC for longer than 14 days, or more often than three times in a 12-month period is not advised unless you are under the supervision of your doctor.

Method of administration

PAZIPEP OTC tablets should be taken in the morning, swallowed whole with little water either before or during breakfast. The gastro-resistant tablet should not be crushed, chewed or broken before swallowing because the coating prevents pH sensitive degradation in the gut.

Use in children and adolescents

These tablets are not recommended for use in children due to limited data on safety and efficacy.

If you take more PAZIPEP OTC than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. There are no known symptoms of overdose however as in any case of overdosage, treatment should be symptomatic and supportive measures should be utilised.

If you forget to take PAZIPEP OTC

Do not take a double dose to make up for a forgotten dose. Take your next normal dose at the usual time.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

PAZIPEP OTC can have side effects.

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

If any of the following happens to you, stop taking PAZIPEP OTC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- severe allergic reaction to PAZIPEP OTC with swelling of the mouth, tongue, or face and/or throat
- difficulty to breathe or swallow
- red lumpy skin rash (hives)
- dizziness which may result in collapse.

These are very serious side effects. If you have them, you may have had a serious reaction to PAZIPEP OTC 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 experience itching, right upper-belly pain, dark urine, yellow skin/eyes (jaundice), (symptoms of liver damage that can lead to liver failure and brain damage (see section 2).
- If you experience unexplained flu-like symptoms with signs of infection/inflammation, such as high temperature, chills, shivering, sore throat, mouth ulcers, headaches, sweating, or weakness, pale skin and/or breathlessness. This may be the result of blood disorders which can be identified through blood tests and can include a sharp drop in circulating granular white blood cells (agranulocytosis), a decrease in white blood cells (leukopenia) or decrease in the blood of the number of red, white cells and platelets (pancytopenia).
- If you develop severe flu-like symptoms followed by severe skin rash, reddening of the skin with blisters or peeling, itching, or hives (elevated patches of red or pale skin that often itch) with flushing or ulcers and bleeding in the lips, eyes, mouth, nose and genitals. This may be associated with a high fever and joint pains (these are signs and symptoms of a sometimes-fatal form of allergic skin disease called Stevens-Johnson syndrome) (see section 2).
- If you develop a severe rash, skin eruption or swelling, with reddening and swelling that may lead to blistering and peeling of the skin and resembles burns (toxic epidermal necrolysis also called Lyell syndrome).
- If you develop any other severe skin reaction, especially in the face, near the eyes and mouth and sometimes in the throat, causing narrowing and difficulty with breathing that can be fatal or red, raised, scaly nonscarring rash on sun-exposed areas (see section 2).
- If you experience problems with passing urine such as a decrease or increase in urine volumes or if you suspect that there is blood in your urine or if you develop a fever and generally feel unwell such as experiencing weakness, nausea and loss of appetite as this may be due to severe kidney problems (acute interstitial nephritis). This can lead to chronic renal failure if it is not diagnosed quickly. Your doctor will likely discontinue your treatment with PAZIPEP OTC (see section 2).

- If you experience severe watery stool/runny tummy that does not go away, sometimes with blood in your stool, stomach pain and fever, you may have developed bowel inflammation caused by a bacterial infection (see section 2).
- If you experience tiredness, a lack of energy and enthusiasm, intermittent muscular spasms or cramps, mental confusion, disorientation, sudden, violent, irregular, involuntary muscle contraction, dizziness and abnormal heart rhythms. These can be symptoms of low blood sodium and low blood magnesium (which may result in low blood calcium and/or blood potassium) and can happen if you are on PAZIPEP OTC for more than three months. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium (see section 2).
- If you experience osteoporotic bone fractures of the hip, wrist or spine (osteoporosis is a condition where certain bones become brittle), (see section 2).

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

- digestive tract problems such as stomach pain, runny tummy (watery stools), constipation and bloating (gas)
- headache (if the headache is severe, it may be necessary to stop treatment with PAZIPEP OTC
- feeling of dizziness or feeling like ‘spinning’
- nausea (feeling sick)
- vomiting
- dry mouth
- feeling abnormally weak and tired
- generally feeling unwell
- hypersensitivity (allergic reactions) (see above)
- not seeing clearly

- blood test results showing impaired liver function
- a skin rash and itching
- increase of certain fats in the blood (triglycerides, cholesterol)
- weight changes
- not sleeping well.

Less-frequent side effects

- decrease in the blood of the number of platelets (thrombocytopenia) (may increase risk of bruising or bleeding)
- feeling down
- feeling disorientated e.g. when you are confused about the time, where you are or even who you are
- taste disorders
- increase in billirubin (formed when red blood cells breakdown)
- joint pain
- muscle pain
- enlargement of breasts in men
- increase in body temperature
- swollen hands, ankles or feet (peripheral oedema).

Side effects occurring with unknown frequency

- seeing, feeling or hearing things that are not there (hallucinations)
- feeling confused or baffled
- skin rash, itchy skin, lumpy rash (hives), oversensitivity to sunlight
- itchy skin rash with blood spots, bruising or discolouring of the skin leading to red patches characterised by bull's-eye-shaped lesions (erythema multiforme)
- muscle spasms
- tingling feelings such as “pins and needles”.

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 healthcare provider. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety PAZIPEP OTC**.**

5. How to store PAZIPEP OTC

Store all medicines out of reach of children.

Store at or below 25 °C in the original packaging.

Do not use after the expiry date stated on the blister/carton after EXP. The expiry date refers to the last day of that month.

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 PAZIPEP OTC contains

The active substance is pantoprazole.

Each PAZIPEP OTC gastro-resistant tablet contains 20 mg pantoprazole (as sodium sesquihydrate).

The other ingredients are

Tablet core:

Calcium stearate

Crospovidone

Mannitol

Silica-colloidal anhydrous

Sodium carbonate anhydrous

Sodium starch glycollate

Sub-coating:

Hypromellose

Macrogol 6000

Sodium hydroxide

Gastro-coating:

Eudragit L30 D55

Macrogol 6000

Film-coating:

Opadry AMB 80W 52172.

What PAZIPEP OTC looks like and contents of the pack

PAZIPEP OTC gastro-resistant tablet is a yellow to pale yellow coloured, oval, biconvex enteric-coated tablet plain on both the sides.

PAZIPEP OTC is supplied in aluminium/aluminium blisters of 14 tablets. The blister is then packaged in an outer carton to give a pack size of 14 tablets.

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