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DR. REDDY'S LABORATORIES (PTY) LTD.
PENTOZ 20 and 40
APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PENTOZ 20 and 40, delayed release film-coated tablets

Pantoprazole sodium sesquihydrate

Contains sugar (mannitol)

Each 20 mg film-coated tablet contains 38,95 mg of mannitol.

Each 40 mg film-coated tablet contains 77,90 mg of mannitol.

Read all of this leaflet carefully before you start taking PENTOZ

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PENTOZ 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 PENTOZ is and what it is used for

2. What you need to know before you take PENTOZ

3. How to take PENTOZ

4. Possible side effects

5. How to store PENTOZ

6. Contents of the pack and other information

1. What PENTOZ is and what it is used for

PENTOZ belongs to a group of medicines known as proton pump inhibitors. Proton pump inhibitors reduce the amount of acid secreted by the stomach.

PENTOZ 20 is used:

- to improve the symptoms and to heal a condition known as mild gastro-oesophageal reflux disease (GORD). In this condition, acid from the stomach (the gut) leaks back into the tube that is between the throat and the stomach (the oesophagus). The symptoms include heartburn, unpleasant, sour

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taste at the top of the throat or in the back of the mouth, coughing and pain when swallowing.

- for long term management of the above condition, and to prevent it from re-occurring.
- to prevent stomach and intestinal lesions and indigestion caused by non-selective medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and inflammation.

PENTOZ 40 is used:

- for short term treatment of
    - ulcers in the stomach or in the first part of the small intestine (the duodenum).
    - inflammation of lining of the tube that is between the throat and the stomach as a result of acid leaking from the stomach (reflux oesophagitis).
    - if ulcers in the small intestine are found to be due to bacteria, treatment with an antibiotic may be given with PENTOZ.
- for the treatment of Zollinger-Ellison syndrome, a disease in which the stomach, as the result of tumours, produces too much acid.

2. What you need to know before you take PENTOZ

Do not take PENTOZ:

- if you are hypersensitive (allergic) to pantoprazole or to any of the other ingredients of PENTOZ (see list under section 6).
- if you have serious liver problems.
- if you are taking medicines for HIV such as atazanavir or nelfinavir (antiretrovirals). These medicines may not work as well against your HIV infection if you take them with PENTOZ.

PENTOZ must not be given to children as it is not known if it is safe and effective for them.

Warnings and precautions

Take special care with PENTOZ.

Tell your doctor before taking PENTOZ:

- if you have low levels of magnesium, potassium and calcium in your blood.
- if you take PENTOZ long term, you may develop a lack of magnesium, potassium and calcium. The symptoms may develop slowly so that you may not notice them and may include tiredness, muscle

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cramps or spasms, dizziness, irregular heartbeats, confusion and fits. Your doctor will recommend that your magnesium and calcium levels be tested before and at intervals during treatment, and may recommend that you take magnesium and calcium supplements.

- if you have or ever had liver problems or jaundice.
- if you suffer from indigestion due to stress or anxiety.
- if you:
  - are unintentionally losing weight,
  - notice you have very dark stools or blood in your stools,
  - have difficulty with or have pain when swallowing,
  - are vomiting blood,
  - feel very tired, especially,
  - if you have or ever had stomach ulcers or digestive tract operations,
  - PENTOZ, when taken in these cases, may relieve and hide the symptoms of a serious condition which needs treatment without delay.
- if you are over 50 years of age or when you take PENTOZ for a long period of time or in high doses, it may cause an increase in risk of bone fractures in the hip, wrist or spine.
- PENTOZ may cause a lack of vitamin B12 if used daily for long periods. Tell your doctor if you ever had a lack of vitamin B12.
- if you experience symptoms such as persistent loose or watery stools, especially if combined with nausea, vomiting, stomach cramps and/or fever.
- if you have or had severe kidney problems.
- PENTOZ can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including PENTOZ, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with PENTOZ. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.
- your doctor may recommend blood tests to monitor your liver and kidney function.
- if you get a rash on your skin or experience signs of an allergic reaction (see section 4, Possible side effects).

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- if you happen to be more sensitive to sunburn, you should take precautions when exposed to sunlight and if you experience joint pain.
- if you are due to have a specific blood test (Chromogranin A).

Other medicines and PENTOZ

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are taking any medicine, and in particular any of the following medicines, consult your doctor or pharmacist before taking PENTOZ:

- Antiretroviral medicines such as atazanavir, ritonavir and nelfinavir (see section 2).
- Blood thinning medicine (warfarin**,** phenprocoumon and acenocoumarol). If you are taking warfarin, phenprocoumon or acenocoumarol to thin your blood, your blood may become too thin if you take it with PENTOZ. Your risk of bleeding may increase. Speak to your doctor as you may need additional tests to check your blood (INR tests).
- Certain medicines may not be absorbed well if taken with PENTOZ and may therefore be less effective e.g.,
  - ketoconazole, itraconazole and posaconazole, used for fungal disease. Thrush and athlete's foot are examples of fungal diseases,
  - erlotinib (medicine to treat cancer).
- High doses of methotrexate (sometimes given for psoriasis, a skin disease marked by red, itchy, scaly patches or for rheumatoid arthritis, a chronic progressive disease-causing inflammation in the joints, or for treatment in certain types of cancers).
- Fluvoxamine (used to treat depression and other psychiatric diseases) - if you are taking fluvoxamine your doctor may reduce the dose.
- St John's wort (*Hypericum perforatum*) (used to treat mild depression), rifampicin (antibiotic that is used to treat or prevent tuberculosis).

PENTOZ with food and drink

PENTOZ can be taken with or without food.

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Speak to your doctor or pharmacist before taking PENTOZ if you are taking alcohol on a regular basis.

Pregnancy and breastfeeding

Do not take PENTOZ tablets if you are pregnant or breastfeeding your baby.

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 health care provider for advice before receiving this medicine.

Driving and using machines

PENTOZ may make you feel dizzy or make you see less clearly.

It is not always possible to predict to what extent PENTOZ may interfere with the daily activities of a patient. You should ensure that you do not drive vehicles or operate any hazardous tools or machines unless you are aware of the measure to which PENTOZ affects you.

PENTOZ contains mannitol

PENTOZ contains mannitol which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using PENTOZ.

PENTOZ contains sodium

PENTOZ 20 contains 1,350 mg sodium per tablet and PENTOZ 40 contains 3,342 mg sodium per tablet.

Thus, this medicine contains less than 1 mmol sodium (23 mg) per dose of one tablet per day.

3. How to take PENTOZ

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

- Always take PENTOZ exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
- If you have the impression that the effect of PENTOZ is too strong or too weak, talk to your doctor or pharmacist.
- Your doctor will tell you how long your treatment with PENTOZ will last. Do not stop treatment early because this may undo the healing positive effects already achieved.

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- PENTOZ is for adults only.
- PENTOZ should be taken in the morning, either before or during breakfast.
- PENTOZ should be swallowed whole with about a quarter glass of water.
- Do not break, crush or chew the tablet.

Your doctor will decide on the most suitable dose and duration of treatment for your condition. He/she may decrease or increase the dose and duration of treatment according to the way you respond to treatment.

If you notice that your symptoms are not being controlled after four weeks of treatment with the prescribed daily dose, further investigation is recommended.

Do not stop treatment early because your condition may worsen.

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

Mild gastro-oesophageal reflux disease (GORD):

One PENTOZ 20 tablet (20 mg) once daily for 4 weeks.

Your doctor will decide if you should continue treatment for another 4 weeks.

Long-term management and prevention of relapse in GORD:

One PENTOZ 20 tablet (20 mg) once daily is recommended, increased to one PENTOZ 40 tablet (40 mg) once daily if relapse occurs. After healing of the relapse, the dose can be reduced to one PENTOZ 20 tablet (20 mg) once daily.

Stomach ulcer:

One PENTOZ 40 tablet (40 mg) once daily, for 4 to 8 weeks.

Duodenal (small intestine) ulcer:

One PENTOZ 40 tablet (40 mg) once daily for 2 to 4 weeks.

An antibiotic may also be given if a bacterial infection is present in the ulcers.

Reflux oesophagitis (inflammation of lining of the tube that is between the throat and the stomach):

One PENTOZ 40 tablet (40 mg) once daily for 4 to 8 weeks.

Zollinger-Ellison Syndrome:

The usual starting dose is 80 mg (two PENTOZ 40 tablets) once daily. This will be adjusted by your doctor based on measurements of the amount of acid secreted.

With doses above 80 mg daily, the dose should be divided and should be taken twice daily (morning and

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evening).

Elderly:

No dosage adjustment is necessary if you are an elderly person.

Kidney and liver problems:

No dose adjustments are required if you have kidney problems.

If you have liver problems that are less serious, you must not take more than the daily dose of one PENTOZ 20 tablet per day (see section 2).

Children:

Safety and efficacy in children have not been established.

If you take more PENTOZ than you should

If you have taken more PENTOZ tablets than you should, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take PENTOZ

Take the missed dose as soon as you remember. If, however, it is almost time for your next dose, do not take a double dose to make up for the missed dose. Continue with the normal dose as prescribed for you.

If you stop taking PENTOZ

Take PENTOZ tablets for the full period of treatment, even if you begin to feel better. Do not stop taking PENTOZ unless your doctor tells you to.

4. Possible side effects

PENTOZ can have side effects.

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

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If any of the following happens to you, stop taking PENTOZ and tell your doctor immediately, or go to the casualty department at your nearest hospital as you will need immediate medical attention or hospitalisation:

- Swelling of the mouth, tongue or face and/or throat, difficulty to breathe or swallow, red lumpy skin rash (hives) and dizziness which may result in collapse, shock or even death.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PENTOZ. 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, black tarry stools, yellow skin/eyes (jaundice), and unexplained flu-like symptoms (symptoms of liver damage that can lead to liver failure).
- If you develop severe flu-like symptoms followed by severe skin blisters with redness around them, or a peeling rash, hives and/or mouth sores: These are symptoms of Stevens-Johnson syndrome, a sometimes-fatal form of allergic skin disease.
- Any other severe skin eruption or swelling, especially in the face, near the eyes and mouth and sometimes in the throat, causing narrowing and difficulty with breathing that can be fatal.
- Problems with passing urine or if you pass urine more often than usual and develop a fever and generally feel unwell, or if you notice blood in your urine, or if you experience painful urination and lower back pain (symptoms of serious inflammation of the kidneys, possibly leading to kidney failure).
- Blurred vision.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache.
- Stomach pain, runny tummy (watery stools), constipation, gas.

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Less frequent effects:

- Decrease in the blood of the number of:
  - red cells, white cells, and platelets (pancytopaenia),
  - white blood cells (leukopaenia) - may increase the risk of inflammation/infection,
  - platelets (thrombocytopaenia) - may increase risk of bruising or bleeding,
  - decrease in circulating granular white blood cells (agranulocytosis) - an acute disease marked by high fever.
- Blood test results showing:
  - impaired liver function,
  - increase of certain fats in the blood (triglycerides, cholesterol),
  - increase in billirubin (formed when red blood cells break down),
  - decrease in calcium.
- Increase in body temperature, weight changes.
- Feeling down/ sad, not sleeping well, feeling confused or baffled.
- Feeling of dizziness or feeling like 'spinning', problems with taste.
- Nausea (feeling sick), vomiting (throwing up), dry mouth, bloating, stomach pain.
- Joint pain, muscle pain, increased risk of wrist, hip and spine-fractures.
- Enlargening of breasts in men.
- Feeling abnormally weak and tired, generally feeling unwell, swollen hands and feet.
- Oversensitivity to sunlight.

Side effects of unknown frequency:

- Runny tummy due to bacterial infections.
- Seeing, hearing or feeling or experiencing things that seem real, but that do not in fact really happen (hallucinations), confusion.
- Feeling of tingling, prickling, pins and needles, burning sensation or numbness.
- Decrease in sodium, magnesium, calcium, potassium and vitamin B12 (when used long term in high doses) in the blood (detected by blood tests).

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

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Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. Health care providers are asked to report any suspected adverse reactions 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.

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

5. How to store PENTOZ

Keep out of the reach and sight of children.

Store at or below 25 °C and protect from light and moisture.

Do not store in bathrooms.

Keep the tablets in the original blisters and keep the blisters in the carton until required for use.

Keep the tablets in the plastic container until required for use and keep the container tightly closed.

Do not use after the expiry date stated on the containers/labels.

Do not use PENTOZ if the tablets have any visible signs of deterioration such as discolouration or chipping.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

The active substance is pantoprazole.

Each PENTOZ 20 film-coated tablet contains pantoprazole sodium sesquihydrate equivalent to pantoprazole 20 mg.

Each PENTOZ 40 film-coated tablet contains pantoprazole sodium sesquihydrate equivalent to pantoprazole 40 mg.

The other ingredients of PENTOZ 20 and PENTOZ 40 are calcium stearate, crospovidone, hydroxypropyl cellulose, methacrylic acid/ethyl acrylate copolymer, sodium carbonate anhydrous, talc, titanium dioxide, triethyl citrate and zein.

The film-coating contains hydroxypropyl methylcellulose, polyethylene glycol (macrogol), synthetic yellow iron oxide and titanium dioxide.

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The black printing ink contains ammonium hydroxide (trace amounts), iron oxide black, propylene glycol and shellac.

What PENTOZ looks like and contents of the pack

PENTOZ 20: Yellow, round, biconvex, film-coated tablets printed with "P20" on one side with black ink and plain on the other side.

PENTOZ 40: Yellow, round, biconvex, film-coated tablets printed with "P40" on one side with black ink and plain on the other side.

The film-coated tablets (30, 90, 100, 500, or 1000) are packed in white HDPE containers. The containers with 30 and 90 tablets have child-resistant, white plastic caps with opening instructions on the top and are packed in cardboard cartons. The containers with 100, 500, or 1000 have white, ribbed, plastic caps with smooth tops.

The film-coated tablets (7, 14 and 10) are packed in silver coloured aluminium/aluminium laminate (polyamide/aluminium/PVC) blister strips then packed in cardboard cartons.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block B, 204 Rivonia Road

Morningside

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Registration numbers

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For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website: http://www.drreddys.co.za