DR REDDY'S LABORATORIES (PTY) LTD.
PENTOZ OTC
APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

PENTOZ OTC, delayed release film-coated tablet

Pantoprazole sodium sesquihydrate

Contains sugar (mannitol)

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

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

PENTOZ OTC film-coated tablets are available without a doctor's prescription for you to treat a mild illness. Nevertheless, you still need to use PENTOZ OTC carefully to get the best results from it.

- 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.
- Do not share PENTOZ OTC with any other person.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet:

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

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

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

PENTOZ OTC is used in adults for the temporary 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 PENTOZ OTC

Do not take PENTOZ OTC:

- if you are hypersensitive (allergic) to pantoprazole or any of the other ingredients of PENTOZ OTC (see list under Section 6);
- if you have a serious liver problem;
- 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 PENTOZ OTC.

PENTOZ OTC 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 OTC**.**

Contact your doctor or speak to your pharmacist before taking PENTOZ OTC:

- if you have low levels of magnesium, potassium and calcium in your blood.
- if you take PENTOZ OTC 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 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 experience symptoms such as persistent loose or watery stools, especially if combined with nausea, vomiting, stomach cramps and/or fever.
- if you suffer from indigestion due to stress or anxiety.
- if you have osteoporosis.
- if you have or ever had liver problems or jaundice.
- 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
- have or ever had stomach ulcers or digestive tract operations.

- PENTOZ OTC, when taken in these cases, may relieve and hide the symptoms of a serious condition which needs treatment without delay.
- PENTOZ OTC 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 get a rash on your skin or experience signs of an allergic reaction (see section 4, Possible side effects).
- if you to be more sensitive to sunburn, you should take precautions when exposed to sunlight and if you experience joint pain.
- if you have severe kidney problems.
- PENTOZ OTC can cause a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including PENTOZ OTC, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with PENTOZ OTC. 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 are due to have a specific blood test (Chromogranin A).

Other medicines with PENTOZ OTC

Always tell your healthcare professional 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 OTC tablets.

- Antiretroviral medicines known 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 OTC. 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 OTC 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 OTC with food and drink

PENTOZ OTC can be taken with or without food.

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

Pregnancy and Breastfeeding

Do not take PENTOZ OTC 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 OTC may make you feel dizzy or make you see less clearly.

It is not always possible to predict to what extent PENTOZ OTC 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 OTC affects you.

PENTOZ OTC contains mannitol

PENTOZ OTC 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 OTC.

3. How to take PENTOZ OTC

Always take PENTOZ OTC exactly as instructed below. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of PENTOZ OTC is too strong or too weak for you, tell your doctor or pharmacist.

PENTOZ OTC is for adults only.

- Take one PENTOZ OTC tablet per day, before or during breakfast.
- PENTOZ OTC should be swallowed whole with about a quarter glass of water.
- Do not break, crush or chew the tablet.
- The maximum dose is one tablet per day for a maximum period of 14 days.
- If your symptoms have not gone away after 14 days of continuous treatment, consult your doctor.
- You should not take more than three 14-day courses of PENTOZ OTC in a 12-month period without consulting your doctor.
- The use of PENTOZ 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.

If you take more PENTOZ OTC than you should

If you have taken more PENTOZ OTC 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 OTC

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 of one tablet per day before or during breakfast.

4. Possible side effects

PENTOZ OTC can have side effects.

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

If any of the following happens to you, stop taking PENTOZ OTC 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), dizziness (which may be as a result of a sudden fall in blood pressure leading to collapse or 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 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, 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.

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,
  - 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 magnesium, sodium, 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.

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 OTC.

5. How to store PENTOZ OTC

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

The other ingredients of the tablets 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 methyl cellulose, polyethylene glycol (macrogol), synthetic yellow iron oxide and titanium dioxide.

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

What PENTOZ OTC looks like and contents of the pack

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

7, 10 or 14 film-coated tablets are packed in white HDPE containers or in aluminium/aluminium blister strips, packed into outer cartons.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

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This leaflet was last revised in

18 January 2024

Registration number

45/11.4.3/0592

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