

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S2

**PYRIDIUM 100 mg (tablets)**

**Phenazopyridine hydrochloride**

**Contains sugar.**

**Each tablet contains 44,30 mg sucrose and 64,26 mg lactose monohydrate**

**Read all of this leaflet carefully because it contains important information for you:**

PYRIDIUM is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use PYRIDIUM carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share PYRIDIUM 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.

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

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

#### **1. What PYRIDIUM is and what it is used for**

PYRIDIUM is used to relieve symptoms caused by irritation of the urinary tract such as pain, burning, and the feeling of needing to urinate urgently or frequently. This medicine does not treat the cause of the urinary irritation, but it can help relieve the symptoms while other treatments take effect. PYRIDIUM is a

dye that works as a painkiller to soothe the lining of the urinary tract.

## **2. What you need to know before you take PYRIDIDIUM**

### **Do not take PYRIDIDIUM if:**

- you are hypersensitive (allergic) to phenazopyridine hydrochloride or any of the other ingredients of PYRIDIDIUM (listed in section 6).
- you suffer from inflammation of blood vessels around the kidney (confirmed by urine testing), urea in the blood (progressive weakness and easy fatigue, loss of appetite due to nausea and vomiting)
- you suffer from impaired renal function
- you suffer from severe inflammation of the liver (hepatitis)
- PYRIDIDIUM should not be used for repeated or prolonged treatment without full diagnostic investigation
- you suffer from glucose-6-phosphate dehydrogenase (G6PD), as deficiency. You are at an increased risk of severe haemolytic anaemia (blood disorder)
- you are pregnant or breastfeeding your baby.

### **Warnings and precautions**

#### **Take special care with PYRIDIDIUM:**

- PYRIDIDIUM is for relief of symptoms and you should not delay the process of determining the underlying cause of your disease. Prompt appropriate treatment of the cause of pain must be instituted. Stop using PYRIDIDIUM if the symptoms are controlled.
- If PYRIDIDIUM is used concurrently with an antibiotic treatment, the duration of PYRIDIDIUM therapy should not exceed 2 days.
- If your symptoms persist or recur, a doctor should be consulted.
- PYRIDIDIUM produces an orange to red colour in the urine and faeces and may stain clothing. Staining of contact lenses has been reported.
- PYRIDIDIUM may affect the results of tests performed to determine the cause of your disease. Inform your doctor that you are taking PYRIDIDIUM prior to being tested.

- You should stop taking PYRIDIUM if your eyes and skin becomes discoloured.

### **Other medicines and PYRIDIUM**

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

PYRIDIUM may affect the results of tests performed to determine the cause of your disease.

Inform you doctor that you are taking PYRIDIUM prior to being tested.

### **PYRIDIUM with food and drink**

PYRIDIUM should be taken with or after meals.

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

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.

The safety and/ or efficacy of the use of PYRIDIUM during pregnancy and breastfeeding have not been established (see section 2).

No fertility studies have been conducted in humans.

### **Driving and using machines**

PYRIDIUM does not appear to influence the ability to drive or use machines; however, it is known to cause visual disturbances.

It is not always possible to predict to what extent PYRIDIUM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which PYRIDIUM affects them.

### **PYRIDIUM contains lactose, sucrose and sodium starch glycolate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PYRIDIUM.

PYRIDIDIUM contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take PYRIDIDIUM**

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

Adults should take two tablets three times per day with or after meals.

If PYRIDIDIUM is used concurrently with an antibiotic treatment, the duration of PYRIDIDIUM therapy should not exceed 2 days.

PYRIDIDIUM is for oral use.

**Tablets should not be chewed.**

#### **If you take more PYRIDIDIUM than you should**

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

The following can occur with an overdosage:

- the presence of a higher-than-normal level of methemoglobin in your blood. The symptoms include shortness of breath, blue or purple colouration of the skin, mental status changes, headache, fatigue, exercise intolerance, dizziness and loss of hairlines
- abnormal breakdown of red blood cells characterised by pallor, fatigue, shortness of breath, and potential for heart failure
- impaired liver function and sometimes kidney failure.

Treatment of overdosage is symptomatic and supportive.

#### **If you forget to take PYRIDIDIUM**

If you forget to use a dose of PYRIDIDIUM, carry on with the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

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

PYRIDIDIUM can have side effects.

Not all side effects reported for PYRIDIDIUM are included in this leaflet.

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

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

- swelling of the hands, feet, ankles, face, lips, mouth, or throat which may cause difficulty in swallowing or breathing,
- a rash or itching,
- fainting,
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PYRIDIDIUM. 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:

- fever, headache and neck stiffness (meningitis).

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

Tell your doctor if you notice any of the following:

- headache
- nausea, vomiting and diarrhoea
- abdominal cramps or stomach pains
- skin discolouration
- tiredness, weakness
- visual disturbances
- crystal deposits in your urinary tract

- discolouration of urine and other body fluids.

### **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 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 of PYRIDIUM.

### **5. How to store PYRIDIUM**

- Store all medicines out of reach of children
- Store at or below 25 °C in a dry place.
- 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 PYRIDIUM contains:**

The active substance is phenazopyridine hydrochloride.

The other ingredients are:

*Tablet core:* lactose monohydrate, starch corn, sodium starch glycolate, hydrogenated vegetable oil and magnesium stearate

*Sugar coating:* sucrose, gelatine, acacia, confectioner’s (icing) sugar, talc, starch corn, Opalux AS26572 brown (consisting of sucrose, FD&C Red no 40 (CI16035) FD&C Blue no. 2 (CI 73015), povidone, titanium dioxide (CI 77891) and sodium benzoate), Polishing wax (consisting of white bees wax, carnauba wax and chloroform).

#### **What PYRIDIUM looks like and contents of the pack**

A shiny, smooth, round, maroon sugar-coated tablet without capping or chipping.

Amber plastic PVC jar with black polyethylene screw cap and pressure sensitive seal, grey sponge and

desiccant.

**Holder of Certificate of Registration**

Biotech Laboratories (Pty) Ltd

Block K West, Central Park

400 16<sup>th</sup> Road, Halfway House

Midrand

Tel no: +27 11 848 3050

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