SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

PYRIDIUM 100 mg (tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 100 mg Phenazopyridine hydrochloride.

Contains sugar. Each tablet contains 44,30 mg sucrose and 64,26 mg lactose monohydrate.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablets.

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Short-term symptomatic relief of pain, burning, urgency and frequency arising from irritation of the lower urinary tract mucosa. These symptoms may result from infection, trauma, surgery, endoscopic procedures, or passage of urethral or uterine sounds (in medicine, a “sound”, is an instrument for probing and dilating passages within the body) or catheters. The underlying cause of the irritation must be determined and treated (e.g. antibacterial therapy for infection).

4.2 Posology and method of administration

Posology

Adults: Two tablets three times daily with or after meals.

When used concurrently with an antibacterial medicine for the treatment of a urinary tract infection, the

duration of PYRIDIUM therapy should not exceed two days.

Method of administration

For oral use.

Tablets should not be chewed.

4.3 Contraindications

- Hypersensitivity to phenazopyridine, or to any of the excipients listed in section 6.1.
- PYRIDIUM is contraindicated in patients with, renal impairment, glomerulonephritis and uraemia.
- PYRIDIUM is contraindicated in patients with severe hepatitis.
- PYRIDIUM should not be used for repeated or prolonged treatment without full diagnostic investigation.
- Glucose-6-phosphate dehydrogenase (G6PD) deficiency patients have an increased risk of severe haemolytic anaemia.
- Safety in pregnancy and lactation has not been established (see section 4.6).

4.4 Special warnings and precautions for use

1. The use of PYRIDIUM for relief of symptoms should not delay definitive diagnosis of the underlying cause. Prompt appropriate treatment of the cause of pain must be instituted and PYRIDIUM should be discontinued when symptoms are controlled.
2. When PYRIDIUM is used concurrently with an antibacterial medicine in the treatment of a urinary tract infection, the duration of PYRIDIUM therapy should not exceed 2 days.
3. If symptoms persist or recur, a doctor should be consulted.
4. PYRIDIUM produces an orange to red colour in the urine and faeces and may stain clothing*. Staining of contact lenses has been reported.
5. PYRIDIUM may mask pathological conditions and interfere with laboratory test values using colourimetric, spectrophotometric or fluorometric analysis methods (see section 4.5).
6. PYRIDIUM may interfere with urinalysis based on colour reactions or spectrometry. May cause false urine sugar and urine ketone test results in diabetics (see section 4.5)

7. Treatment should be stopped if the skin or sclera becomes discoloured. This may indicate accumulation as a result of impaired renal excretion.

**A 0,25 % solution of sodium hydrosulphite (available from photographic development outlets) has been used to remove phenazopyridine stains.*

Excipients

PYRIDIUM contains lactose and sucrose.

Patients with the rare hereditary problems of galactose and fructose intolerance e.g. galactosaemia, total lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take PYRIDIUM.

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

4.5 Interaction with other medicines and other forms of interaction

PYRIDIUM may mask pathological conditions and interfere with laboratory test values using colourimetric, spectrophotometric or fluorometric analysis methods.

PYRIDIUM may interfere with urinalysis based on colour reactions or spectrometry. May cause false urine sugar and urine ketone test results in diabetics.

There are no known interactions between PYRIDIUM and other medicine.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and/or efficacy during pregnancy has not been established.

Breastfeeding

Safety and/or efficacy during breastfeeding has not been established.

Fertility

No fertility studies have been conducted in humans.

4.7 Effects on the ability to drive and use machines

PYRIDIUM does not appear to influence the ability to drive or use machines; however, it is known to cause visual disturbances. Patients taking PYRIDIUM should ensure that their ability to drive and use machines is not affected by PYRIDIUM before engaging in such activities.

4.8 Undesirable effects

Tabulated list of adverse reactions

MedDRA System Organ Class (SOC)	**Frequency**	**Description**
Blood and lymphatic system disorders	*Frequency unknown*	Methaemoglobinaemia, haemolytic anaemia, potential haemolytic medicine in G6PD deficiency, sulfhaemoglobinaemia.
Immune system disorders	*Frequency unknown*	Anaphylactoid reactions and hypersensitive hepatitis.
Nervous system disorders	*Frequency unknown*	Headache, aseptic meningitis with bouts of fever and confusion.
Eye disorders	*Frequency unknown*	Visual disturbances.
Gastrointestinal disorders	*Frequency unknown*	Gastrointestinal effects, nausea, vomiting and diarrhoea.
Hepato-biliary disorders	*Frequency unknown*	Hepatic toxicity usually associated with overdose, jaundice.
Skin and subcutaneous tissue disorders	*Frequency unknown*	Rash, pruritus, discolouration.

Renal and urinary disorders	*Frequency unknown*	Acute renal failure usually associated with overdose or with therapeutic doses in patients with renal impairment, crystal deposits of phenazopyridine in the urinary tract. Urine is tinged either orange or red (see section 4.4).
General disorders and administrative site conditions	*Frequency unknown*	Abnormal discolouration of body fluids.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/ risk balance of the medicine. Healthcare 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.

4.9 Overdose

Exceeding the recommended dose in patients with normal renal function or administering the recommended dose to patients with impaired renal function (common in elderly patients) may lead to increased serum levels and toxic reactions.

Methaemoglobinaemia generally follows a massive, acute overdose, for which cyanosis is an aid in diagnosis. Methylene blue, 1 to 2 mg/kg bodyweight given intravenously as a 1 % solution, may be used to treat the methaemoglobinaemia. Methylene blue will usually lead to a reduction of the methaemoglobinaemia and disappearance of the cyanosis.

Oxidative Heinz body haemolytic anaemia also may occur, and "bite cells" (degmacytes) may be present in a chronic overdosage situation.

Red blood cell G6PD deficiency may predispose to haemolysis; however, haemolysis may occur at normal doses in patients with G6PD Mediterranean.

Hepatic impairment and occasional renal failure may also occur.

Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A.18 Medicines acting on genito-urinary system.

Phenazopyridine has an analgesic action on the urinary tract and alleviates the symptoms of dysuria, frequency, burning and urgency. Phenazopyridine is excreted in the urine where it exerts a topical analgesic effect on the mucosa of the urinary tract.

5.2 Pharmacokinetic properties

Phenazopyridine hydrochloride is absorbed from the gastrointestinal tract. Up to 90 % of a dose is excreted within 24 hours, 65 % as unchanged phenazopyridine and 18 % as paracetamol.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Lactose monohydrate

Starch corn

Sodium starch glycolate.

Hydrogenated vegetable oil

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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special precautions.

7 HOLDER OF CERTIFICATE OF REGISTRATION

Biotech Laboratories (Pty) Ltd.

Block K West, Central Park

400 16th Road, Halfway House

Midrand

8 REGISTRATION NUMBER

H/18/1728

9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

Date of registration: 11 October 2000

10 DATE OF REVISION OF THE TEXT

11 June 2024.