**UTISED** 

**Tablets** 

## Composition

Each tablet contains Phenazopyridine hydrochloride 100 mg.

## **Action**

Phenazopyridine is known to have a direct topical analgesic effect on the mucosa lining of the urinary tract. The kidneys directly into the urine rapidly excrete it. 65% of an oral dose will be secreted directly into the urine chemically unchanged.

#### **Indications**

Utised is indicated for the symptomatic relief of pain, burning, urgency, frequency and other discomfort arising from irritation of the mucosa of the lower urinary tract. These symptoms may result from infection, trauma, surgery, endoscopic procedures or catheters.

## **Contraindications**

- Hypersensitivity to phenazopyridine.
- Contra-indicated in glomerulonephritis, uremia, impaired renal function and severe hepatitis.
- Phenazopyridine 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.

### Warnings

- 1. The use of phenazopyridine 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 phenazopyridine should be discontinued when symptoms are controlled.
- 2. When phenazopyridine used concurrently with an antibacterial agent in the treatment of a urinary tract infection, the duration of phenazopyridine therapy should not exceed 2 days.
- 3. If symptoms persist or recur, a doctor should be consulted.

# **Pregnancy**

Category B

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

#### **Nursing Mothers**

It is not known whether phenazopyridine passes into the breast milk. However, phenazopyridine has not been reported to cause problems in nursing babies.

#### **Adverse Reactions**

at the level of over dosage.

Headache, rash, pruritus, and occasional gastrointestinal disturbances may occur. Methemoglobinemia, hemolytic anemia, and renal and hepatic toxicity have been described, usually

## **Precautions**

Phenazopyridine produces an orange to red colour in the urine and faeces and may stain clothing. Staining of contact lenses has been reported. A yellowish colour of the skin or sclerae may indicate accumulation of phenazopyridine resulting from impaired renal function and necessitates discontinuance of the drug.

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

May cause false urine sugar and urine ketone test results in diabetics.

# **Dosage and Administration**

The adult dosage is 2 tablets 3 times daily, after meals. The dosage in children is 1 tablet up to three times daily, after meals.

When used concomitantly with an antibacterial agent for the treatment of a urinary tract infection, the administration of Utised should not exceed 2 days.

# **Over Dosage**

### Manifestations

Methemoglobinemia generally follows a massive, acute overdose.

Oxidative Heinz body hemolytic anemia may also occur, and "bite cells" may be present in a chronic over dosage situation.

## **Treatment**

Administer methylene blue, 1-2 mg/kg body weight intravenously, or ascorbic acid, 100-200 mg orally. This should result in prompt reduction of the methemoglobinemia and disappearance of cyanosis, which is an aid in diagnosis.

## **Presentation**

Box of 20 tablets.