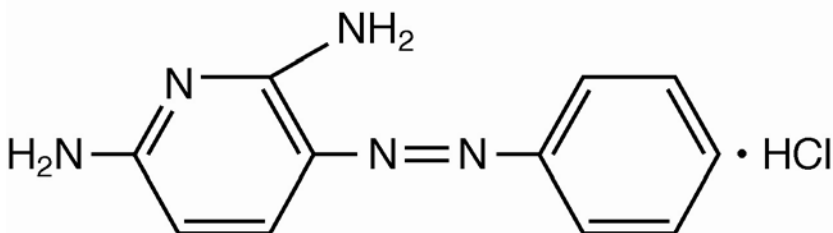


## Pyridium® (Phenazopyridine HCl Tablets, USP)

### RX Only

#### DESCRIPTION:

Pyridium® (Phenazopyridine Hydrochloride) is chemically designated 2,6-Pyridinediamine, 3-(phenylazo), monohydrochloride. It is a urinary tract analgesic agent for oral administration. Phenazopyridine Hydrochloride tablets contain 100 mg or 200 mg Phenazopyridine Hydrochloride. Also contains lactose hydrous, sodium starch glycolate, corn starch, hydrogenated vegetable oil, silicon dioxide, magnesium stearate, sugar, gelatin, FD&C red #40 aluminum lake, titanium dioxide, FD&C blue #2 aluminum lake, povidone, sodium benzoate, carnauba wax and white wax.



$C_{11}H_{11}N_5 \cdot HCl$

M.W. 249.70

#### CLINICAL PHARMACOLOGY:

Phenazopyridine Hydrochloride is excreted in the urine where it exerts a topical analgesic effect on the mucosa of the urinary tract. This action helps to relieve pain, burning, urgency and frequency. The precise mechanism of action is not known.

The pharmacokinetic properties of Phenazopyridine Hydrochloride have not been determined. Phenazopyridine is rapidly excreted by the kidneys, with as much as 65% of an oral dosage being excreted unchanged in urine.

#### INDICATIONS AND USAGE:

Pyridium is indicated for the symptomatic relief of pain, burning, urgency, frequency and other discomforts arising from irritation of the lower urinary tract mucosa caused by infection, trauma, surgery, endoscopic procedures, or the passage of sounds or catheters. The use of Phenazopyridine Hydrochloride for relief of symptoms should not delay definitive diagnosis and treatment of causative conditions. Because it provides only symptomatic relief, prompt appropriate treatment of the cause of pain must be instituted and Phenazopyridine Hydrochloride should be discontinued when symptoms are controlled.

The analgesic action may reduce or eliminate the need for systemic analgesics or narcotics. It is, however, compatible with antibacterial therapy and can help to relieve pain and discomfort during the interval before antibacterial therapy controls the infection. Treatment of a urinary tract infection with Phenazopyridine Hydrochloride should not exceed 2 days because there is a lack of evidence that the combined administration of Phenazopyridine Hydrochloride and an antibacterial provides greater benefit than administration of the antibacterial alone after 2 days. (See **DOSAGE and ADMINISTRATION** Section)

**CONTRAINDICATIONS:**

Phenazopyridine Hydrochloride should not be used in patients who have previously exhibited hypersensitivity to it. The use of Phenazopyridine Hydrochloride is contraindicated in patients with renal insufficiency.

**PRECAUTIONS:**

**General:** A yellowish tinge of the skin or sclera may indicate accumulation due to impaired renal excretion and the need to discontinue therapy.

The decline in renal function associated with advanced age should be kept in mind.

**Information for Patients:** Phenazopyridine Hydrochloride produces an orange to red color in the urine and may stain fabric. Staining of contact lenses has been reported.

**Laboratory Test Interactions:** Due to its properties as an azo dye, Phenazopyridine Hydrochloride may interfere with urinalysis based on spectrometry or color reactions.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term administration of Phenazopyridine Hydrochloride has induced neoplasia in rats (large intestine) and mice (liver). Although no association between Phenazopyridine Hydrochloride and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted.

**Pregnancy Category B:** Reproduction studies have been performed in rats at doses up to 50 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus due to Phenazopyridine Hydrochloride. There are however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Nursing Mothers:** No information is available on the appearance of Phenazopyridine Hydrochloride or its metabolites in human milk.

**ADVERSE REACTIONS:**

Headache, rash, pruritus and occasional gastrointestinal disturbance. An anaphylactoid-like reaction has been described. Methemoglobinemia, hemolytic anemia, renal and

hepatic toxicity have been reported, usually at overdose levels (see **OVERDOSAGE** section).

**OVERDOSAGE:**

Exceeding the recommended dose in patients with good renal function or administering the usual dose to patients with impaired renal function (common in elderly patients), may lead to increased serum levels and toxic reactions. Methemoglobinemia generally follows a massive, acute overdose. Methylene blue, 1 to 2 mg/kg body weight intravenously, should cause prompt reduction of the methemoglobinemia and disappearance of the cyanosis which is an aid in diagnosis. Oxidative Heinz body hemolytic anemia may also occur, and "bite cells" (degmacytes) may be present in a chronic overdosage situation. Red blood cell G-6-PD deficiency may predispose to hemolysis. Renal and hepatic impairment and occasional failure, usually due to hypersensitivity, may also occur.

**DOSAGE and ADMINISTRATION:**

100 mg tablets: Adult dosage is two tablets 3 times a day after meals.

200 mg tablets: Adult dosage is one tablet 3 times a day after meals.

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

**HOW SUPPLIED:**

Pyridium<sup>®</sup> (Phenazopyridine Hydrochloride Tablets, USP) is supplied as follows:

100 mg - maroon, round tablets imprinted "WC 180"

Bottles of 100: N 0430-0180-24

200 mg – maroon, round tablets imprinted "WC 181"

Bottles of 100: N 0430-0181-24

**Store at controlled room temperature 15° to 30° C (59° to 86° F)[See USP].**

Manufactured by:

Actavis Totowa LLC

Totowa, NJ 07512 USA

Marketed by:

Warner Chilcott (US), Inc.

Rockaway, NJ 07866

1-800-521-8813



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