PHENAZOPYRIDINE HYDROCHLORIDE - phenazopyridine tablet
ECI Pharmaceuticals, LLC

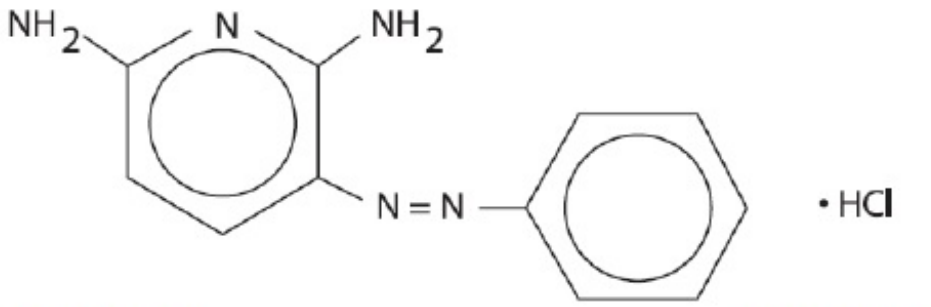
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

PHENAZOPYRIDINE HYDROCHLORIDE TABLETS, USP
Rx Only

CAUTION: Federal law prohibits dispensing without prescription.

DESCRIPTION

Phenazopyridine Hydrochloride is light or dark red to dark violet, odorless, slightly bitter, crystalline powder. It has a specific local analgesic effect in the urinary tract, promptly relieving burning and pain. It has the following structural formula:



$C_{11}H_{11}N_5 \cdot HCl$ M.W. 249.70

Phenazopyridine HCl Tablets, USP contain the following inactive ingredients: carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone and pregelatinized starch.

CLINICAL PHARMACOLOGY

Phenazopyridine HCl 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 HCl have not been determined. Phenazopyridine HCl is rapidly excreted by the kidneys, with as much as 66% of an oral dose being excreted unchanged in the urine.

INDICATIONS AND USAGE

Phenazopyridine HCl 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 HCl 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 HCl 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 HCl should not exceed two days because there is a lack of evidence that the combined administration of Phenazopyridine HCl and an antibacterial provides greater benefit than administration of the antibacterial alone after two days. (See DOSAGE AND ADMINISTRATION section.)

CONTRAINDICATIONS

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

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 overdosage levels (see OVERDOSAGE Section).

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.

NOTE: Patients should be informed that Phenazopyridine HCl produces a reddish-orange discoloration of the urine and may stain fabric. Staining of contact lenses has been reported.

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

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term administration of Phenazopyridine HCl has induced neoplasia in rats (large intestine) and mice (liver).

Although no association between Phenazopyridine HCl 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 HCl. 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 HCl, or its metabolites in human milk.

DOSAGE AND ADMINISTRATION

100 mg Tablets: Average adult dosage is two tablets 3 times a day after meals.

200 mg Tablets: Average 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 HCl should not exceed 2 days.

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 or ascorbic acid 100 to 200 mg given orally 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.

HOW SUPPLIED

100 mg Tablets: Supplied in bottles of 100 (NDC 51293-801-01) counts.

Appearance: Deep brown to maroon colored, round, film coated tablets debossed “AN” above “1” on one side and plain on the other.

200 mg Tablets: Supplied in bottles of 100 (NDC 51293-802-01) counts.

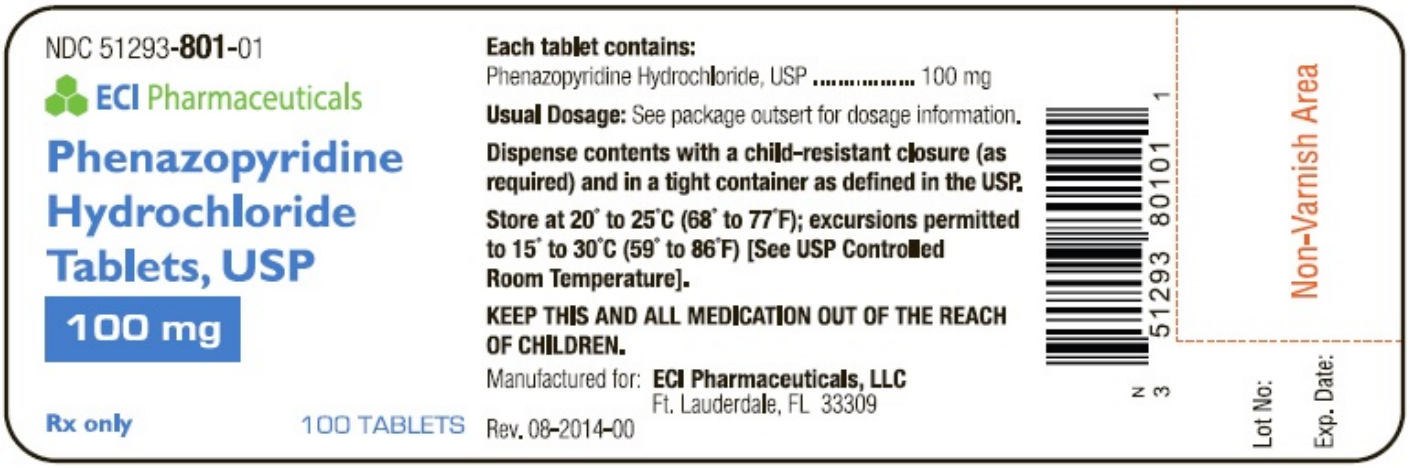
Appearance: Deep brown to maroon colored, round, film coated tablets debossed “AN” above “2” on one side and plain on the other.

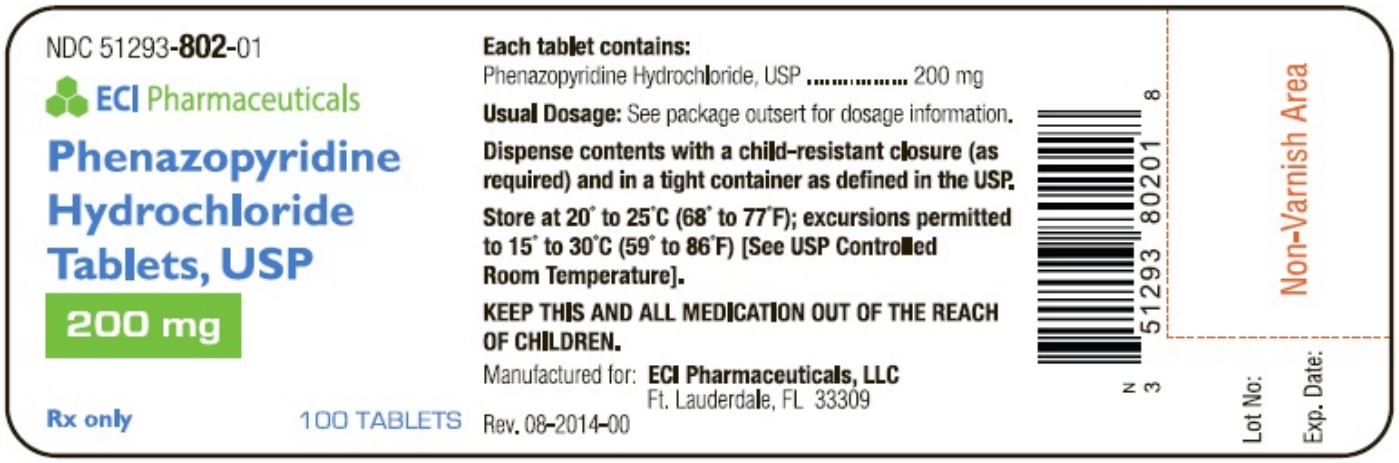
DISPENSE contents with a child-resistant closure (as required) and in a tight container as defined in the USP.

STORE at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Manufactured for:
ECI Pharmaceuticals, LLC
Fort Lauderdale, FL 33309

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





PHENAZOPYRIDINE HYDROCHLORIDE

phenazopyridine tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51293-801
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics			
Color	BROWN (MAROON)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	AN;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51293-801-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		02/01/2011	

PHENAZOPYRIDINE HYDROCHLORIDE

phenazopyridine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51293-802
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	200 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONES (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	BROWN (MAROON)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	AN;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51293-802-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		02/01/2011	

Labeler - ECI Pharmaceuticals, LLC (962476029)

Registrant - ECI Pharmaceuticals, LLC (962476029)

Revised: 10/2014 ECI Pharmaceuticals, LLC