PHENAZOPYRIDINE HYDROCHLORIDE- phenazopyridine tablet
Proficient Rx LP

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.

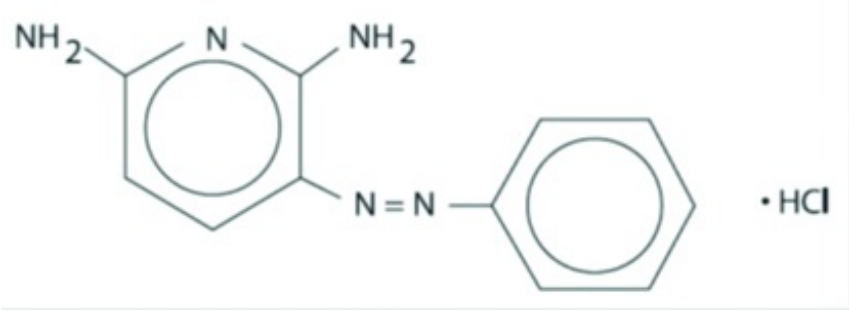
PHENAZOPYRIDINE HYDROCHLORIDE TABLETS, USP

Rx Only

CAUTION: Federal law prohibits dispensing without prescription.

DESCRIPTION

Phenazopyridine Hydrochloride, USP 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:



$C_{11}H_{11}N_5$•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, 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 2 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 2 days (see **Error! Hyperlink reference not valid.** 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 **Error! Hyperlink reference not valid.** section).

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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.

Carcinogenicity, Mutagenicity, 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

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

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

Phenazopyridine HCl tablets, USP **200 mg** are available as deep brown to maroon colored, round, film-coated tablets debossed “PY” above “2” on one side and plain on the other.
They are supplied as follows:

Bottles of 6	NDC 71205-813-06
Bottles of 10	NDC 71205-813-10
Bottles of 12	NDC 71205-813-12
Bottles of 20	NDC 71205-813-20
Bottles of 24	NDC 71205-813-24

Bottles of 30	NDC 71205-813-30
Bottles of 60	NDC 71205-813-60
Bottles of 90	NDC 71205-813-90

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

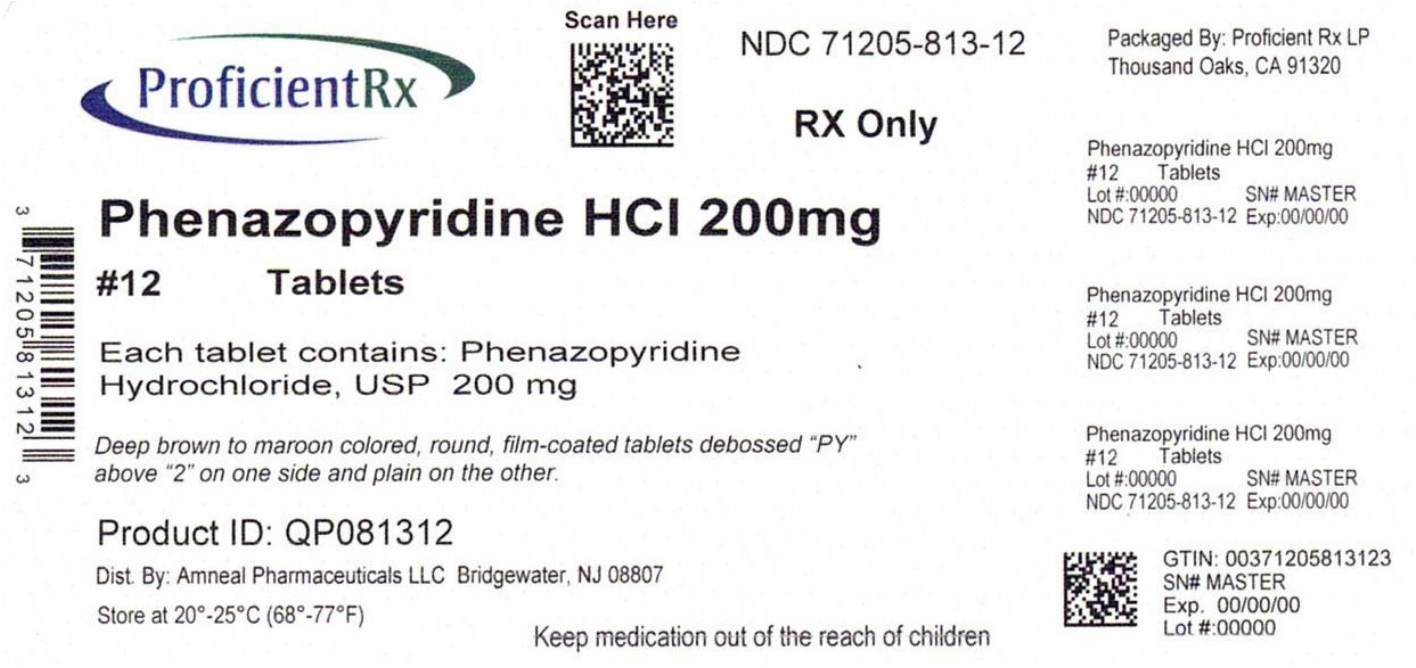
STORE at 20° to 25°C (68° to 77°F); excursions permitted between15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Distributed by:
Amneal Pharmaceuticals LLC
Bridgewater, NJ 08807

Repackaged by:
Proficient Rx LP
Thousand Oaks, CA 91320

Rev. 06-2020-01

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



PHENAZOPYRIDINE HYDROCHLORIDE

phenazopyridine tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71205-813(NDC:65162-682)
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)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 1000 (UNII: U076Q6Q621)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-813-06	6 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2023	
2	NDC:71205-813-10	10 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2023	
3	NDC:71205-813-12	12 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2023	
4	NDC:71205-813-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2023	
5	NDC:71205-813-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2023	
6	NDC:71205-813-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2023	
7	NDC:71205-813-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2023	
8	NDC:71205-813-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/14/2023	

Marketing Information

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

other		02/01/2011	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(71205-813) , RELABEL(71205-813)

Revised: 6/2023 Proficient Rx LP