PHENAZOPYRIDINE HYDROCHLORIDE- phenazopyridine hydrochloride tablet, coated
Pageview Pharmaceuticals

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.

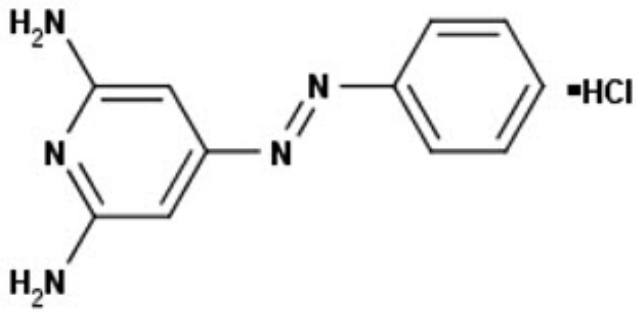
PHENAZOPYRIDINE HCL 100 mg and 200 mg
Phenazopyridine Hydrochloride Tablet

For Oral Administration
Rx Only

DESCRIPTION

Phenazopyridine Hydrochloride is a red-brown, odorless, slightly bitter, crystalline powder. It has a specific local analgesic effect in the urinary tract, promptly relieving burning and pain.

Structural formula:



Formula = $C_{11}H_{11}N_5$ •HCl
M.W. 249.72

Phenazopyridine HCl oral tablets contain the following inactive ingredients: Calcium Phosphate, Sodium Starch Glycolate and Magnesium Stearate.

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.

INDICATIONS AND USAGE

Phenazopyridine HCl is indicated for the symptomatic relief of pain, burning, urgency frequency, and other discomforts arising from irritation of the mucosa of the lower urinary tract caused by infection, trauma, surgery, endoscopic procedures, or the passage of sounds or catheters.

The use of phenazopyridine for relief of symptoms should not delay definitive diagnosis and treatment of causative conditions. The drug should be used for symptomatic relief

of pain and not as a substitute for specific surgery or antimicrobial therapy.

Phenazopyridine is compatible with antimicrobial therapy and can help relieve pain and discomfort during the interval before antimicrobial therapy controls the infection.

Treatment of a urinary tract infection with phenazopyridine should not exceed 2 days. There is no evidence that the combined administration of phenazopyridine and an antimicrobial provides greater benefit than administration of the antimicrobial alone after 2 days. (See Dosage and Administration.)

CONTRAINDICATIONS

In patients who are hypersensitive to the drug or its ingredients. Phenazopyridine is contraindicated in patients with renal insufficiency, severe liver disease, severe hepatitis or pyelonephritis of pregnancy.

It should be used cautiously in the presence of GI disturbances.

PRECAUTIONS

The patient should be advised that phenazopyridine produces an orange to red color in the urine and feces, and may cause staining. Phenazopyridine may cause discoloration of body fluids and staining of contact lenses has been reported. A yellowish color of the skin or sclera may indicate accumulation of phenazopyridine resulting from impaired renal function and necessitates discontinuance of the drug. It should be noted that a decline in renal function is common in elderly patients. Phenazopyridine may mask pathological conditions and interfere with laboratory test values using colorimetric, spectrophotometric or fluorometric analysis methods.

Cautious use in patients with G-6-PD deficiency is advised since these patients are susceptible to oxidative hemolysis and may have greater potential to develop hemolytic anemia.

Information for Patients

The patient should be advised to take phenazopyridine with or following food or after eating a snack to reduce stomach upset.

The patients should be aware that phenazopyridine causes a reddish orange discoloration of the urine and feces, and may stain clothing. Phenazopyridine may cause discoloration of body fluids and staining of contact lenses has been reported. There have been reports of teeth discoloration when the product has been broken or held in the mouth prior to swallowing.

Patients should be instructed to take phenazopyridine for only 2 days if an antibacterial agent is administered concurrently for the treatment of a urinary tract infection. If symptoms persist beyond those 2 days, the patient should be instructed to contact his or her physician.

Laboratory Tests

Phenazopyridine may interfere with laboratory test values using colorimetric, photometric or fluorometric analysis methods.

Altered urine laboratory test values may include ketone (sodium nitroprusside), bilirubin (foam test, talc-disk-Fouchet-spot test, Franklin's tablet-Fouchet test, p-nitrobenzene diazonium p-toluene sulfonate reagent), diacetic acid (Gerhardt ferric chloride test), free hydrochloric acid, glucose (glucose oxidase tests), 17-hydroxycorticosteroids (modified Glenn-Nelson), 17-ketosteroids (Holtorff Koch modification of Zimmerman), porphyrins, albumin (discolors bromophenol blue test areas of commercial reagent strips, nitric acid ring test), phenolsulfophthalein, urobilinogen (color interference with Ehrlich's reagent), and urinalysis (spectrophotometric or color-based tests). Phenazopyridine also imparts an orange-red color to stools which may interfere with color tests.

Drug Interactions

The interaction of phenazopyridine with other drugs has not been studied in a systematic manner. However, the medical literature to date suggests that no significant interactions have been reported Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term administration of phenazopyridine has been associated with tumors of the large intestine in rats and of the liver in mice. Available epidemiological data are insufficient to evaluate the carcinogenicity of phenazopyridine in humans. In vitro studies indicate that phenazopyridine in the presence of metabolic activation is mutagenic in bacteria and mutagenic and clastogenic in mammalian cells.

Pregnancy Category B

Reproductive studies with phenazopyridine (in combination with sulfacytine) in rats given up to 110 mg/kg/day and in rabbits given up to 39 mg/kg/day during organogenesis revealed no evidence of harm to offspring.

One prospective study in humans demonstrated that phenazopyridine traverses the placenta into the fetal compartment. There are no adequate and well-controlled studies in pregnant women. Therefore, phenazopyridine should be used in pregnant women only if the benefit clearly outweighs the risk.

Nursing Mothers

It is not known whether phenazopyridine or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of drug therapy to the mother.

Children

Adequate and well-controlled studies have not been performed in the pediatric population. No pediatric-specific problems have been documented.

ADVERSE REACTIONS

The following adverse events have been reported:

CNS: headache.

Gastrointestinal: nausea, vomiting and diarrhea.

Dermatologic and Hypersensitivity: rash, pruritus, discoloration, anaphylactoid-like reaction and hypersensitivity hepatitis

Hematologic: methemoglobinemia, hemolytic anemia, potential hemolytic agent in G-6-PD deficiency, sulfhemoglobinemia.

Other: visual disturbances, renal and hepatic toxicity usually associated with overdose, renal calculi, jaundice, discoloration of body fluids and aseptic meningitis.

OVERDOSAGE

Symptoms: 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. Methemoglobinemia generally follows a massive, acute overdose. Methylene blue, 1 to 2 mg/kg/dose given intravenously as a 1% solution as needed, should cause prompt reduction of the methemoglobinemia and disappearance of the cyanosis which is an aid in diagnosis. Oxidative Heinz body hemolytic anemia also may occur, and "bite cells" (degmacytes) may be present in a chronic overdosage situation. Red blood cell G-6-PD deficiency may predispose to hemolysis; however, hemolysis may occur at normal doses in patients with G-6-PD Mediterranean.

Renal toxicity and occasional failure and hepatic impairment may also occur.

Treatment: Treatment is symptomatic and supportive.

DOSAGE AND ADMINISTRATION

Adults: 200 mg 3 times daily after meals. When used concomitantly with an antibacterial agent for the treatment of a urinary tract infection, the administration of phenazopyridine should not exceed 2 days. If symptoms persist, the patient should be re-evaluated.

HOW SUPPLIED

100 mg Tablets: Supplied in bottles of 100 count NDC# 73028-201-01.

Appearance: Reddish-brown, round tablets debossed "C1" on one side and plain on the reverse side.

200 mg Tablets: Supplied in bottles of 100 count NDC# 73028-202-01.

Appearance: Redish-brown, round tablets debossed "C7" on one side and plain on the reverse side.

STORAGE

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

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center

immediately.

PHARMACIST: This product is not an Orange Book rated product, therefore all prescriptions using this product shall be subject to state and federal statutes as applicable. This product has not been subjected to FDA therapeutic or other equivalency testing. There are no claims of bioequivalence or therapeutic equivalence. Each person recommending a prescription substitution using this product shall make such recommendation based on his/her professional knowledge and opinion, upon evaluating the active ingredients, inactive ingredients, excipients and chemical information contained within the enclosed prescribing information.

Rx Only

Manufactured for:
Pageview Pharmaceuticals, LLC
Maryland Heights, MO 63146

Rev._____

PRINCIPAL DISPLAY PANEL - 100 mg Tablet Bottle Label

PAGEVIEW
PHARMACEUTICALS

Oral Tablets

Phenazopyridine
Hydrochloride, USP

100 mg

100 Tablets Rx Only

NDC 00000-000-00

Made and analyzed in the USA

PRINCIPAL DISPLAY PANEL - 200 mg Tablet Bottle Label

PAGEVIEW
PHARMACEUTICALS

Oral Tablets

Phenazopyridine
Hydrochloride, USP

200 mg

100 Tablets Rx Only

NDC 00000-000-00

Made and analyzed in the USA

PHENAZOPYRIDINE HYDROCHLORIDE

phenazopyridine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73028-201
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

Product Characteristics			
Color	ORANGE (Orange-red)	**Score**	no score
Shape	ROUND	**Size**	4mm

Flavor		**Imprint Code**	C1
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73028-201-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/01/2020	

PHENAZOPYRIDINE HYDROCHLORIDE

phenazopyridine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:73028-202
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

Product Characteristics			
Color	ORANGE (Orange-red)	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	C7
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73028-202-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/01/2020	

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Category	Citation	Date	Date
UNAPPROVED DRUG OTHER		12/01/2020	

Labeler - Pageview Pharmaceuticals (117003305)

Revised: 1/2022 Pageview Pharmaceuticals