PHENAZOPYRIDINE HYDROCHLORIDE 100 MG- phenazopyridine hydrochloride tablet
GRAXCELL PHARMACEUTICAL, 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 tablet, film coated - 100 mg, 70795-1241

INDICATIONS AND USAGE

Phenazopyridine 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.)

DOSAGE AND ADMINISTRATION

100 mg Tablets: Average adult dosage is two tablets 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.

INACTIVE INGREDIENTS

Phenazopyridine HCl Tablets, USP contains the following inactive ingredients: croscarmellose sodium, colloidal silicon dioxide, hydroxypropyl methyl cellulose, magnesium stearate, maize (corn starch) microcrystalline cellulose, polyethylene glycol, povidone and pregelatinized starch.

GRAXCELL PHARMACEUTICAL, LLC.

NDC 70795-1241-0

Phenazopyridine Hydrochloride Oral Tablet, USP

Each tablet contains:
Phenazopyridine HCL. USP.....100 mg

100 mg **Rx Only 100 Tablets**

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Manufactured by:
GRAXCELL PHARMACEUTICAL LLC
136 Oak Drive Syosset , N.Y. 11791

Distributed by:
GRAXCELL PHARMACEUTICAL LLC
130 Knickerbocker Avenue Suite J,
Bohemia, NY 11716
P069 (REV:12 - 20)

Phenazopyridine tablet, film coat

Graxcell Pharmaceuticals LLC

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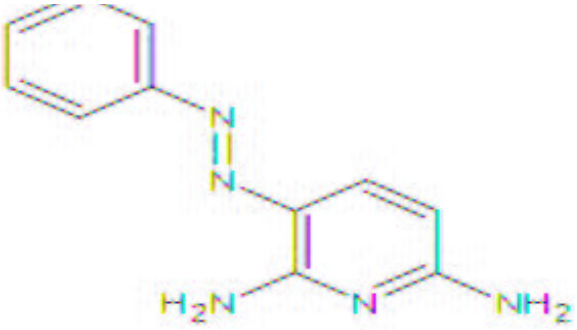
the FDA website at: https://www.fda.gov/dr
forcement-activities-fda/unapproved-drugs

(Phenazopyridine Hydrochl
Tablets, USP)
Rx Only

CAUTION: Federal law prohibits dispensin
prescription.
DESCRIPTION Phenazopyridine Hydrochlor
or dark red to dark violet, odorless, slightl
crystalline powder. It has a specific local a
effect in the urinary tract, promptly relievi
and pain. It has the following structural fo



C11 H11 N5 • HCl M

PHENAZOPYRIDINE HYDROCHLORIDE 100 MG

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70795-1241
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**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	G15
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70795-1241-0	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/12/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/12/2020	

Labeler - GRAXCELL PHARMACEUTICAL, LLC (056556923)

Revised: 12/2021 GRAXCELL PHARMACEUTICAL, LLC