PREFERRED MAXIMUM STRENGTH URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet

Preferred Pharmaceuticals Inc.

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.

DRUG FACTS

Active ingredient (in each tablet)

Phenazopyridine Hydrochloride 97.5 mg.

Purpose

Urinary Analgesic

Warnings

Do not exceed recommended dosage

Ask doctor before use if you have

- kidney disease
- allergies to food, preservatives or dyes
- had a hypersensitive reaction to phenazopyridine

Caution: Do not use this product if you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your physician

When using this product

- stomach upset may occur, taking this product with or after meals may reduce stomach upset
- your urine will become reddish-orange in color. This is not harmful, but care should be taken to avoid staining clothing or other items.

Stop use and ask doctor if

- your symptoms last for more than 2 days
- you suspect you are having an adverse reaction to the medication

If pregnant or breast feeding,

Ask a health professional before use.

Keep out of reach of children

In case of an overdose, get medical help or contact a Poison Control Center right away.

Use

Fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

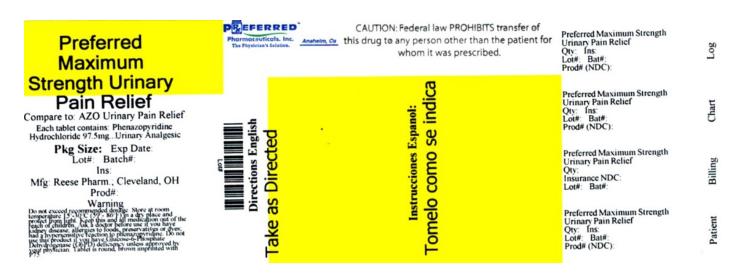
Inactive ingredients

Corn Starch, Croscarmellose Sodium, hypromellose, Lactose, Magnesium Silicate, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene glycol, Polyvinylpyrrolidone, Pregelatinized Starch, Silicon Dioxide and Sodium Starch Glycolate.

Directions

- adults and children 12 years and over: take 2 tablets 3 times daily with a full glass of water, with or after meals as needed
- children under 12 years: consult a doctor
- Do not use for more than 2 days (12 tablets) without consulting a doctor

Principal Display Panel



PREFERRED MAXIMUM STRENGTH URINARY PAIN RELIEF phenazopyridine hydrochloride tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENAZO PYRIDINE HYDRO CHLO RIDE (UNII: 0 EWG668 W17) (PHENAZO PYRIDINE - UNII: K2J09 EMJ52)	PHENAZO PYRIDINE HYDRO CHLO RIDE	97.5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
MAGNESIUM SILICATE (UNII: 9B9691B2N9)		

Product Characteristics				
Color	bro wn	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	P75	
Contains				

1	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8980-	6 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/15/2016	
2	NDC:68788-8980-1	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/15/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Unapproved drug other		06/15/2016		

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8980)	

Revised: 2/2019 Preferred Pharmaceuticals Inc.