PREFERRED URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet Reese Pharmaceutical Co

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

Phenazopyridine Hydrochloride 95 mg

Purpose

Urinary Analgesic

Uses

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

Warning

Do not exceed recommended dosage

Ask Doctor before use if you have

- kidney disease
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine

When using this product

- 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 a 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 the reach of children

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

Directions

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

Inactive Ingredients

lactose, magnesium silicate, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, and sodium starch glycolate. May also contain: corn starch,

croscarmellose sodium, polyvinylpyrrolidone, pregelatinized starch and silicon dioxide.



PREFERRED URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

Product Information

HUMAN OTC DRUG NDC:10956-551 **Product Type** Item Code (Source)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) **PHENAZ OPYRIDINE** 95 mg

(PHENAZ OPYRIDINE - UNII: K2J09EMJ52)

HYDROCHLORIDE

Inactive Ingredients			
Ingredient Name	Strength		
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
SHELLAC (UNII: 46N107B710)			
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)			
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)			

LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	

Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	P95	
Contains				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:10956- 551-30	1 in 1 CARTON	07/27/2016				
1		30 in 1 BLISTER PACK; Type 0: Not a Combination Product					

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2013	

Labeler - Reese Pharmaceutical Co (004172052)

Registrant - Reese Pharmaceutical Co (004172052)

Revised: 12/2022 Reese Pharmaceutical Co