RUGBY PHENAZOPYRIDINE HCL URINARY TRACT ANALGESIC- phenazopyridine hydrochloride tablet
Rugby Laboratories

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

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

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

Long-term administration of phenazopyridine hydrochloride has induced neoplasia in rats (large intestine) and mice (liver). Although no association between Phenazopyridine hydrochloride and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted.

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 1-800-222-1222.

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**

Other Information

■ this product may stain contact lenses
■ this product can interfere with laboratory tests including urine, glucose (sugar), and ketones test
■ Store at room temperature 15-30C (59-86°F) in a dry place and protect from light

Inactive Ingredients

lactose, corn starch, croscarmellose sodium, microcrystalline

cellulose, hypromellose, magnesium stearate, polyethylene glycol, polyvinylpyrrolidone, sodium starch glycolate,

pregelatinized starch, silicon dioxide, talc, and triacetin.

RUGBY PHENAZOPYRIDINE HCL URINARY TRACT ANALGESIC

phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0536-1411
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	95 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TRIACETIN (UNII: XHX3C3X673)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1411-07	1 in 1 CARTON	12/07/2023	
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		12/07/2023	

Labeler - Rugby Laboratories (079246066)

Registrant - Reese Pharmaceutical Co (004172052)

Revised: 12/2023 Rugby Laboratories