LEADER URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet
Cardinal Health

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.

LEADER URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49781-031

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**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B71O)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:49781-031-30	1 in 1 CARTON		
1		30 in 1 BLISTER PACK		

Marketing Information

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

Labeler - Cardinal Health (097537435)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(49781-031) , repack(49781-031)