

LEADER MAXIMUM STRENGTH 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 (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.

Apregnancy test and consultation with a health professional if pregnancy is confirmed is recommended prior to 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



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phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:4978 1-139
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	97.5 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	P97
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-139-12	1 in 1 CARTON		
1		12 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		01/15/2015	

Labeler - Cardinal Health (097537435)**Registrant** - Reese Pharmaceutical Co (004172052)**Establishment**

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(49781-139) , repack(49781-139)

Revised: 1/2014

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