

**CVS HEALTH MAXIMUM STRENGTH 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](#).*

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**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



# CVS HEALTH MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10956-523
<b>Route of Administration</b>	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

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	P97
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-523-24	2 in 1 CARTON	01/15/2015	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:10956-523-12	1 in 1 CARTON	01/15/2015	
2		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** - Reese Pharmaceutical Co. (004172052)

**Registrant** - Reese Pharmaceutical Co (004172052)

**Establishment**

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(10956-523) , repack(10956-523)

Revised: 1/2016

Reese Pharmaceutical Co.