

**PREFERRED 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](#).*

-----

**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

**Urinary Pain Relief**  
**MAXIMUM STRENGTH**

**Preferred**  
**MAXIMUM STRENGTH**  
**Urinary Pain Relief**  
Phenazopyridine Hydrochloride 97.5 mg

**COMPARE AND SAVE!**

**Prompt Relief of Urinary Pain, Burning & Urgency**

- Fast Relief for Urinary Pain
- More Active Ingredient for Maximum Relief

**4 TABLETS**

Knockout for Expiration Date and Lot Number  
0 23513 55110 4

**Urinary Pain Relief**  
**MAXIMUM STRENGTH**

**Caution:** Tablets sealed in blister. Do not use if blister is opened or damaged.

**Drug Facts**

Active ingredient (in each tablet)	Purpose
Phenazopyridine Hydrochloride 97.5 mg	Urinary Tract Analgesic

**Use:** Fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections. Treatment should not exceed 2 days; see Directions.

**Warnings**

**Do not exceed recommended dosage**

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

**Ask a doctor before use if you have**

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

**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 reach of children.** In case of an overdose, get medical help or contact a Poison Control Center right away.

**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
- Do not use for more than 2 days (12 tablets) without consulting a doctor
- children under 12 years: consult a doctor

**Other information**

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

**Inactive ingredients** corn starch, croscarmellose sodium, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, talc and triacetin.

Distributed By  
**Reese Pharmaceutical** • 1-800-321-7178  
10617 Frank Ave., Cleveland, OH 44106  
www.reesepharmaceutical.com  
info@reesepharmaceutical.com

Rev. 9/18 AMAX24R

Questions or Comments Call  
1-800-321-7178, weekdays, 9am-4pm EST

▲ WARNING: This product can expose you to phenazopyridine hydrochloride, which is known to the state of California to cause cancer. For more information, visit www.P60Warnings.ca.gov

Glue Margin - No text or ink of any kind here

# PREFERRED MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:10956-333
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	P75
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10956-333-12	1 in 1 CARTON	01/15/2015	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:10956-333-24	2 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(10956-333) , repack(10956-333)

Revised: 2/2019

Reese Pharmaceutical Co