

**TOPCARE MAXIMUM STRENGTH URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet**  
**TOPCO ASSOCIATES LLC**

*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 99.5 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

**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**

Lactose, magnesium silicate, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, 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



# TOPCARE MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-510
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>PHENAZOPYRIDINE HYDROCHLORIDE</b> (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	99.5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>LACTOSE</b> (UNII: J2B2A4N98G)	
<b>MAGNESIUM SILICATE</b> (UNII: 9B9691B2N9)	

## Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	9mm

<b>Flavor</b>		<b>Imprint Code</b>	p99	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-510-12	1 in 1 CARTON	11/14/2019	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		01/04/2010		

**Labeler** - TOPCO ASSOCIATES LLC (006935977)

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

Revised: 12/2024

TOPCO ASSOCIATES LLC