

**FOSTER AND THRIVE MAXIMUM STRENGTH URINARY PAIN RELIEF-  
phenazopyridine hydrochloride tablet  
Strategic Sourcing Services 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**

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

**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

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.

**Use**

Fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

**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

**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



## FOSTER AND THRIVE MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70677-1230
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

### 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>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70677-1230-1	1 in 1 CARTON	07/20/2023	
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		07/20/2023	

**Labeler** - Strategic Sourcing Services LLC (116956644)

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