

**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

NDC 70677-1230-1      COMPARE TO THE ACTIVE INGREDIENT IN AZO URINARY PAIN RELIEF<sup>®</sup> MAXIMUM STRENGTH<sup>™</sup>

Foster & Thrive<sup>™</sup>  
MAXIMUM STRENGTH  
**Urinary Pain Relief**  
Phenazopyridine Hydrochloride 99.5 mg  
URINARY TRACT ANALGESIC

Relief for Urinary Pain, Burning & Urgency

- Strongest UTI Pain Reliever Available Without a Prescription<sup>1</sup>
- Even Higher Dose for Maximum Relief<sup>1</sup>
- Targets the Source of Pain

ACTUAL SIZE  
**12 TABLETS**

AMONG OUR URINARY PAIN RELIEF PRODUCTS

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.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

\*This product is not manufactured or distributed by DSM IP Assets BV, owner of the registered trademark AZO Urinary Pain Relief<sup>®</sup> Maximum Strength.

**DANGER EVIDENT: TABLETS SEALED IN BLISTER. DO NOT USE IF BLISTER IS OPENED OR DAMAGED.**

Drug Facts	
<b>Active ingredient (in each tablet)</b> Phenazopyridine Hydrochloride 99.5 mg	<b>Purpose</b> Urinary Tract Analgesic
<b>Use</b> Fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections. Treatment should not exceed 2 days; see Directions	
<b>Warnings</b>	
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	
<b>When using this product</b> ■ 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.	
<b>Stop use and ask a doctor if</b> ■ 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. <b>Keep out of reach of children.</b> In case of an overdose, get medical help or contact a Poison Control Center right away 1-800-222-1222.	
<b>Directions</b> ■ 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	
<b>Other information</b> ■ 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	
<b>Inactive ingredients</b> corn starch, croscarmellose sodium, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, talc, triacetin	

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You may report serious side effects to 833-358-6431 Monday to Friday 9:00am to 7:00pm EST

# FOSTER AND THRIVE MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70677-1230
<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>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<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>TRACETIN</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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		07/20/2023	

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

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

Revised: 6/2024

Strategic Sourcing Services LLC