

**RUGBY PHENAZOPYRIDINE HCL URINARY TRACT ANALGESIC- phenazopyridine hydrochloride tablet**  
**Rugby Laboratories**

*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**

Phenazopyridine Hydrochloride 95 mg

**Purpose**

Urinary Analgesic

**Uses**

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

**Warning**

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 foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine

**When using this product**

- 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 the reach of children**

in case of an overdose, get medical help or contact a Poison Control Center right away 1-800-222-1222.

### **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**

### **Other Information**

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

### **Inactive Ingredients**

lactose, corn starch, croscarmellose sodium, microcrystalline

cellulose, hypromellose, magnesium stearate, polyethylene glycol, polyvinylpyrrolidone, sodium starch glycolate,

pregelatinized starch, silicon dioxide, talc, and triacetin.

**95 mg**  
Phenazopyridine Hydrochloride  
Urinary Tract Analgesic



NDC 0536-1411-07  
Compare to the active ingredient in AZO Urinary Pain Relief\*\*

# Phenazopyridine Hydrochloride

Urinary Tract Analgesic

**95 mg**

**Fast relief for urinary discomfort**

**Relief of:**  
Minor Pain, Burning & Urgency

Actual Size



**30 Tablets**

**Warnings:** 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)

**Questions or Comments Call**  
1-800-321-7178, weekdays, 9am-4pm EST  
\*This product is not manufactured or distributed by DSI IP Assets B.V., owner of the registered trademark AZO Urinary Pain Relief\*\*.

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

**Drug Facts**

**Active ingredient (in each tablet)** Phenazopyridine Hydrochloride 95 mg **Purpose** 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**

- kidney disease
- allergies to foods, 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 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 1-800-222-1222.

**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:  
**RUGBY® LABORATORIES**  
Indianapolis, IN 46268  
Questions or comments? Call (800) 618-2471  
[www.majorpharmaceuticals.com](http://www.majorpharmaceuticals.com)

RESECODE

## RUGBY PHENAZOPYRIDINE HCL URINARY TRACT ANALGESIC

phenazopyridine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0536-1411
<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	95 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>LACTOSE</b> (UNII: J2B2A4N98G)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDWL4)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

**Product Characteristics**

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	P95
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1411-07	1 in 1 CARTON	12/07/2023	
1		30 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		12/07/2023	

**Labeler** - Rugby Laboratories (079246066)**Registrant** - Reese Pharmaceutical Co (004172052)

Revised: 12/2023

Rugby Laboratories