

## **URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet KROGER COMPANY**

*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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### **Urinary Pain Relief Tablets**

#### **Drug Facts**

#### **Active ingredient (in each tablet)**

Phenazopyridine Hydrochloride 95 mg

#### **Purpose**

Urinary tract analgesic

#### **Uses**

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 HCl has induced neoplasia in rats (large intestine) and mice (liver). Although no association between Phenazopyridine HCl and human neoplasia has been reported, adequate epidemiological studies along these

lines have not been conducted.

**If pregnant or breastfeeding**, ask a health professional before use. **A pregnancy test and consultation with a health professional if pregnancy is confirmed is recommended prior to 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 or after meals as needed for up to two days. Take with a full glass of water. **Do not use for more than 2 days (12 tablets) without consulting a doctor**
- **Children under 12 years:** Do not use without consulting a doctor

### **Other information**

- This product can interfere with laboratory tests including urine, glucose (sugar), and ketones tests
- This product may stain contact lenses and other items if handled after touching tablets.
- Store at room temperature between 15°C -30°C (59°F -86°F) in a dry place and protect from light.

### **Inactive ingredients**

colloidal silicone dioxide, gum acacia extra pure, hydroxy propyl methyl cellulose, lactose monohydrate, magnesium stearate, maize starch, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate

### **Questions or comments?**

call **1-800-632-6900**

DISTRIBUTED BY THE KROGER CO.  
CINCINNATI, OHIO 45202

### **PRINCIPAL DISPLAY PANEL - 95 mg Tablet Blister Pack Carton**

\*Compare to active ingredient of AZO<sup>®</sup> URINARY  
PAIN RELIEF MAXIMUM STRENGTH \*see back panel  
NDC XXXXX-XXX-XX

Urinary  
Pain Relief

Phenazopyridine  
Hydrochloride 95 mg

FAST RELIEF

FOR URINARY  
DISCONFORT

actual  
size

30 TABLETS

\*Compare to active ingredient of **AZO® URINARY PAIN RELIEF MAXIMUM STRENGTH** \*see back panel  
NDC XXXXX-XXX-XX

# Urinary Pain Relief

Phenazopyridine  
Hydrochloride 95 mg

**FAST RELIEF  
FOR URINARY  
DISCONFORT**

actual  
size



**30 TABLETS**

**Urinary Pain Relief**  
Phenazopyridine Hydrochloride 95 mg

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**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.**

**Drug Facts**

<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Phenazopyridine Hydrochloride 95 mg.....	Urinary tract analgesic

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

**Warnings:**  
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DISTRIBUTED BY THE KROGER CO.  
CINCINNATI, OHIO 45202  
QUALITY GUARANTEE  
800-632-6900 / www.kroger.com

\* This product is not manufactured or distributed by i-Health Inc., distributor of AZO Urinary Maximum Strength Pain Relief®

CTXXXXXXXXXX REV.00-032021

Made in India

**Urinary Pain Relief**  
Phenazopyridine Hydrochloride 95 mg

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)

LOT:  
EXP:



<b>URINARY PAIN RELIEF</b> phenazopyridine hydrochloride tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30142-757
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			

Ingredient Name		Basis of Strength	Strength	
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)		PHENAZOPYRIDINE HYDROCHLORIDE	95 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
STARCH, CORN (UNII: O8232NY3SJ)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)				
Product Characteristics				
Color	BROWN	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	S159	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-757-30	1 in 1 CARTON	05/01/2021	
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		05/01/2021		

**Labeler** - KROGER COMPANY (006999528)