

**MAXIMUM STRENGTH 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.*

-----

**Maximum Strength Urinary Pain Relief**

***Drug Facts***

**Active ingredient (in each tablet)**

Phenazopyridine Hydrochloride 99.5 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 - 99.5 mg Tablet Blister Pack Carton**

COMPARE TO the active ingredient of AZO<sup>®</sup> URINARY PAIN RELIEF<sup>®</sup> MAXIMUM STRENGTH \*See back panel

NDC 30142-756-24

Kroger<sup>®</sup>

OUR PHARMACIST RECOMMENDED

Maximum Strength

Urinary  
Pain Relief

Phenazopyridine  
Hydrochloride 99.5 mg

FAST RELIEF FOR  
URINARY PAIN,  
BURNING &  
URGENCY

Strongest UTI  
Pain Reliever  
Available Without  
a Prescription<sup>†</sup>

Even Higher Dose  
for Maximum Relief<sup>†</sup>

Targets the Source of Pain

actual  
size

<sup>†</sup>Among our urinary  
pain relief products

24 TABLETS

COMPARE TO the active ingredient of AZO URINARY PAIN RELIEF® MAXIMUM STRENGTH \*See back panel

NDC 30142-756-24



Maximum Strength

# Urinary Pain Relief

Phenazopyridine Hydrochloride 99.5 mg

**FAST RELIEF FOR URINARY PAIN, BURNING & URGENCY**

Strongest UTI Pain Reliever Available Without a Prescription†

Even Higher Dose for Maximum Relief†

Targets the Source of Pain

actual size



†Among our urinary pain relief products

**24 TABLETS**



Urinary Pain Relief

Maximum Strength

Phenazopyridine Hydrochloride 99.5 mg

Phenazopyridine Hydrochloride 99.5 mg

# Urinary Pain Relief

Maximum Strength



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

## Drug Facts

### Active ingredient (in each tablet)

Phenazopyridine Hydrochloride 99.5 mg.....Urinary tract analgesic

### Purpose

**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 (1-800-222-1222).

**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 silicon dioxide, cornstarch, gum acacia, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate

**Questions or comments? 1-800-632-6900**

DISTRIBUTED BY THE KROGER CO.  
CINCINNATI, OHIO 45202

MADE IN INDIA

\*AZO URINARY PAIN RELIEF® IS A REGISTERED TRADEMARK OF DSM-IP ASSETS. DSM-IP ASSETS IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT.

FOR MORE PRODUCT INFORMATION,  
SCAN UPC USING YOUR KROGER APP  
OR CALL 800-632-6900

CT3014275624  
REV.00-032021

Our Brands. Our Guarantee.  
Love It or Your Money Back.  
www.kroger.com



Maximum Strength

# Urinary Pain Relief

Phenazopyridine Hydrochloride 99.5 mg

WARNING: This product can expose you to chemicals including phenazopyridine hydrochloride, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.



READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

LOT:

EXP:

100% SIZE	
12-digit UPC-A	
(non-suppressed)	
For Position Only	
0 4 1 2 6 0	0 1 3 1 0 2

## MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:30142-756

<b>Route of Administration</b>	ORAL
--------------------------------	------

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Phenazopyridine Hydrochloride</b> (UNII: 0EWG668W17) (Phenazopyridine - UNII:K2J09EMJ52)	Phenazopyridine Hydrochloride	99.5 mg

<b>Inactive Ingredients</b>	
<b>Ingredient Name</b>	<b>Strength</b>
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>Hypromellose, Unspecified</b> (UNII: 3NXW29V3WO)	
<b>Lactose Monohydrate</b> (UNII: EWQ57Q8I5X)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Starch, Corn</b> (UNII: O8232NY3SJ)	
<b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>Povidone, Unspecified</b> (UNII: FZ989GH94E)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Sodium Starch Glycolate Type A</b> (UNII: H8AV0SQX4D)	

<b>Product Characteristics</b>			
<b>Color</b>	BROWN	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	S160
<b>Contains</b>			

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-756-24	1 in 1 CARTON	05/01/2021	
1		24 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		05/01/2021	

**Labeler** - KROGER COMPANY (006999528)