

**MAXIMUM STRENGTH URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet**  
**TARGET CORPORATION**

*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.*

-----

**up&up maximum strength<sup>†</sup> urinary pain relief**

***Drug Facts***

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

Phenazopyridine Hydrochloride 99.5 mg

***Purpose***

Urinary tract analgesic

***Use***

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 Hydrochloride

**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 20°C -25°C (68°F -77°F) in a dry place and protect from light.

### ***Inactive ingredients***

colloidal silicone dioxide, gum acacia extra pure, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, maize starch, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate.

### ***Questions?***

**1-800-910-6874**

**Compare to** the active ingredient in **AZO® Urinary Pain Relief Maximum Strength\***

maximum strength UTI pain reliever available without a prescription†

**up&up**

†Among our over-the-counter urinary pain relief products

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

**READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

245 03 0248 R01 C-002016-01-009

Dist. by Target Corp., Mpls., MN 55403

**Product of India** TM & ©2023 Target Brands, Inc.

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

**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)

## Packaging

NDC 11673-270-24

# maximum strength<sup>†</sup> urinary pain relief

phenazopyridine hydrochloride 99.5 mg  
urinary tract analgesic

**Compare to the active ingredient in  
AZO® Urinary Pain Relief Maximum Strength\***

relief for urinary pain and burning  
maximum strength UTI pain reliever  
available without a prescription<sup>†</sup>



24 TABLETS

<sup>†</sup>Among our over-the-counter urinary pain relief products

maximum strength<sup>†</sup>  
urinary pain relief

phenazopyridine hydrochloride 99.5 mg

24 TABLETS

\*Among our over-the-counter urinary pain relief products

maximum strength<sup>†</sup>  
urinary pain relief

phenazopyridine hydrochloride 99.5 mg

24 TABLETS

\*Among our over-the-counter urinary pain relief products

maximum strength<sup>†</sup>  
urinary pain relief

phenazopyridine hydrochloride 99.5 mg

24 TABLETS

\*Among our over-the-counter urinary pain relief products

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

**Drug Facts**

Active ingredient (in each tablet)	Purpose
Phenazopyridine Hydrochloride 99.5 mg	Urinary tract analgesic

**Use** 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 Hydrochloride

**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 20°C -25°C (68°F -77°F) in a dry place and protect from light.

**Inactive ingredients** colloidal silicone dioxide, gum acacia extra pure, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, maize starch, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate.

**Questions? 1-800-910-6874**

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

245 03 0248 R01 C-002016-01-009      \*This product is not manufactured or distributed by i-Health Inc.  
Dist. by Target Corp., Mpls., MN 55403      distributor of AZO® Urinary Pain Relief  
**Product of India** TM & ©2023 Target Brands, Inc.      CT1167327024 REV.00-062022

LOT: \_\_\_\_\_  
EXP: \_\_\_\_\_



3 70692 00088 7

## MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11673-270
<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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ACACIA</b> (UNII: 5C5403N26O)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I3O)	
<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)	

### Product Characteristics

<b>Color</b>	brown (Dark Brown)	<b>Score</b>	no score
<b>Shape</b>	RECTANGLE	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	S160
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-270-24	1 in 1 CARTON	01/25/2023	
1		24 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		01/25/2023	

**Labeler** - TARGET CORPORATION (006961700)

Revised: 2/2023

TARGET CORPORATION