

**AZO URINARY TRACT HEALTH- phenazopyridine hydrochloride tablet**  
**i-Health, Inc.**

*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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**AZO Urinary Tract Health**

***Active Ingredient (in each tablet)***

Phenazopyridine Hydrochloride 95 mg

***Purpose***

Urinary tract analgesic

***Use*** Relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

***Warnings***

**Please read insert for important precautions.**

**Ask a doctor before use if you have**

- kidney disease
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine Hydrochloride
- Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency
- sensitivities to lactose

**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.

**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 older: 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: 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 soft contact lenses and other items if handled after touching tablets
- Store at room temperature (59-86 degrees F) in a dry place and protect from light.

**Tamper evident:** Product is sealed within blisters. Do not use if any part of the blister is torn, open or damaged.



**AZO**  
Urinary Pain Relief  
URINARY TRACT HEALTH

**Fast Relief for Urinary Pain**

**AZO**

**Urinary Pain Relief™**  
URINARY TRACT HEALTH

- RELIEVES PAIN, BURNING & URGENCY
- TARGETS THE SOURCE OF PAIN



24 Tablets  
95 mg Phenazopyridine Hydrochloride

Most Trusted Brand based on Nielsen data through 11/02/13

COATING FREE AREA

**AZO**

Urinary Pain Relief™  
URINARY TRACT HEALTH

ASBM7455-1

Contains the #1 doctor recommended ingredient to help relieve urinary pain and discomfort

**Drug Facts**

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Urinary tract analgesic

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**Inactive ingredients** Lactose, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, sodium starch glycolate and talc.

**Información y instrucciones en Español adjuntas**



Distributed by H-Health, Inc. 55 Seebeth Drive, Cromwell, CT 06416  
Country of origin: U.S.

Size and color of tablets may vary.

For questions, concerns, or to report an adverse event, call (800) 722-3476  
[www.azoproducts.com](http://www.azoproducts.com)

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Urinary Pain Relief  
URINARY TRACT HEALTH

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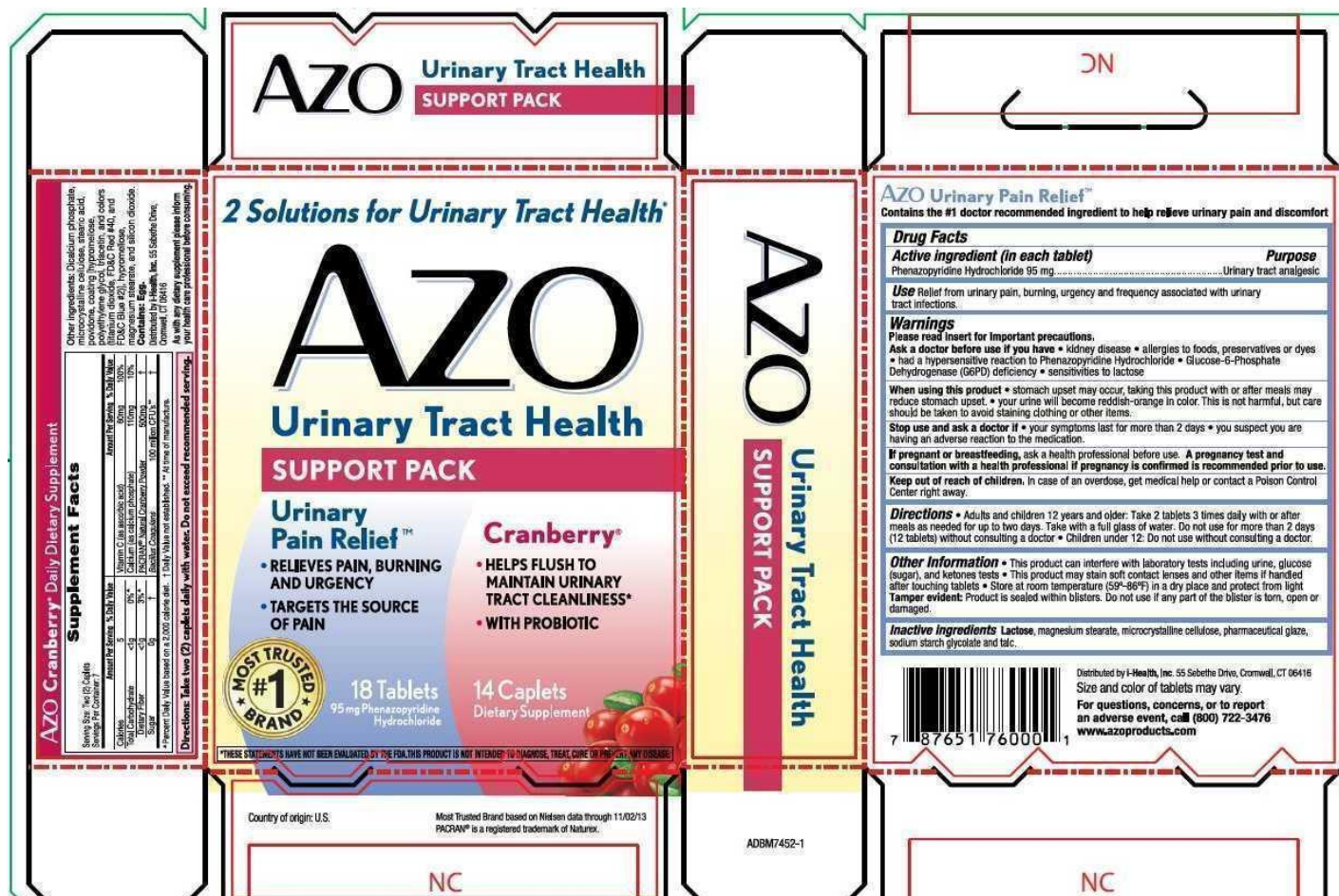
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## AZO URINARY TRACT HEALTH

phenazopyridine hydrochloride tablet

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49973-760
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	95 mg

### Inactive Ingredients

Ingredient Name	Strength
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B710)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	brown (Maroon)	<b>Score</b>	no score
<b>Shape</b>	ROUND (Tablet)	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	W
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49973-760-32	9 in 1 BOX		
1		2 in 1 BLISTER PACK		
2	NDC:49973-760-30	15 in 1 PACKAGE		
2		2 in 1 BLISTER PACK		
3	NDC:49973-760-24	12 in 1 PACKAGE		
3		2 in 1 BLISTER PACK		
4	NDC:49973-760-12	6 in 1 PACKAGE		
4		2 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/28/2014	

**Labeler** - i-Health, Inc. (061427694)

## Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corporation		057795122	manufacture(49973-760)

Revised: 3/2014

i-Health, Inc.