AZO- urinary pain relief 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.

AZO Urinary Pain Relief

Drug Facts

Active ingredient (in each tablet)

Phenazopyridine Hydrochloride 95 mg

Purpose

Urinary 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.

Caution: Do not use this product if you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your physician.

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
- your symptoms last for more than 2 days
- you suspect you are having an adverse reaction to the medication.

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 or 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 F) in a dry place and protect from light
- Tamper evident: tablets sealed in blisters. Do not use if blister foil or seal is open or damaged.

Inactive ingredientsmicrocrystalline cellulose, pregelatinized corn starch, hypromellose, povidine, croscarmellose sodium, polyethylene glycol, carnauba wax and vegetable magnesium stearate. May

also contain corn starch.

Distributed by **i-Health, Inc.**

55 Sebethe Drive, Cromwell, CT 06416

Made in India.

Most Trusted Brand based on Nielsen data through 3/23/2013.

For questions, concerns, or to report an adverse event, call (800) 722-3476

www.azoproducts.com

AZO

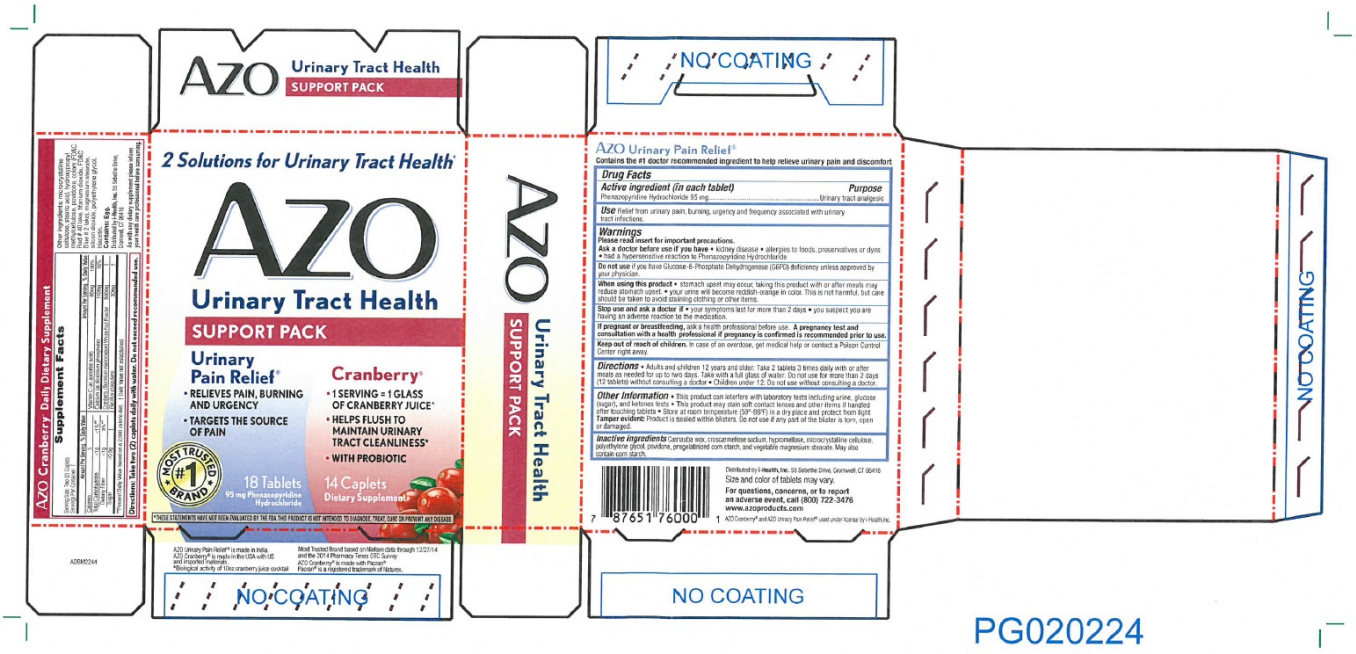
Urinary Pain Relief

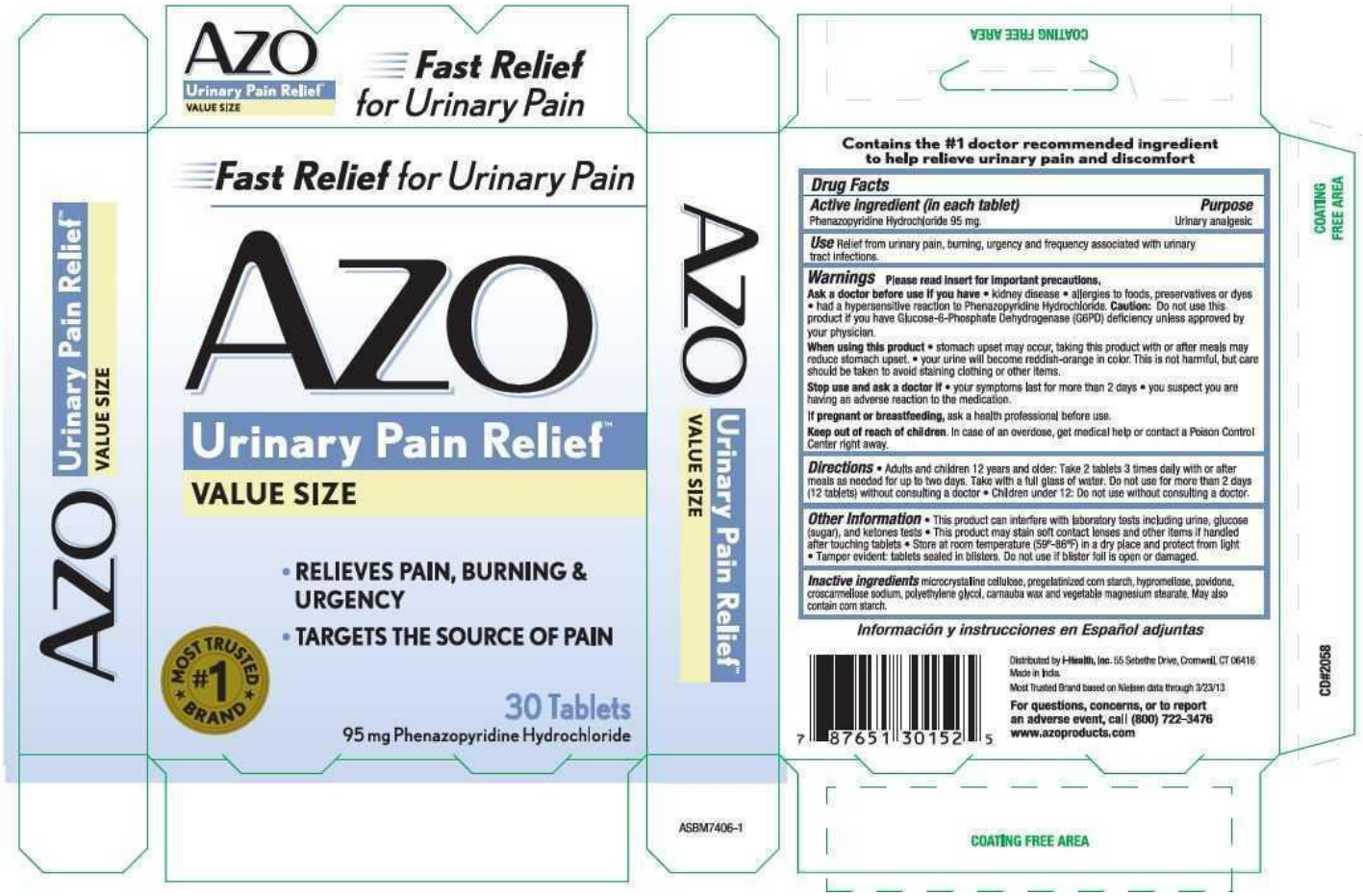
- Relieves pain, burning & urgency
- Targets the source of pain

#1 Most Trusted Brand

Tablets

95 mg Phenazopyridine Hydrochloride





AZO

urinary pain relief tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49973-301
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics			
Color	brown (Maroon)	**Score**	no score
Shape	ROUND (Tablet)	**Size**	7mm
Flavor		**Imprint Code**	W
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49973-301-31	15 in 1 BOX	05/24/2012	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:49973-301-30	15 in 1 BOX	05/24/2012	12/01/2020
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:49973-301-32	1 in 1 BOX	11/11/2017	11/30/2020
3		18 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		05/24/2012	

Labeler - i-Health, Inc. (061427694)

Revised: 12/2020 i-Health, Inc.