

MAXIMUM STRENGTH URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet
Advanced Rx LLC

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

Use

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

Warnings

Do not exceed recommended dosage.

Ask a doctor before use if you have:

- kidney disease
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine Hydrochloride

Do not use 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 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 hydrochloride has induced neoplasia in rats (large intestine) and mice (liver). Although no association between phenazopyridine hydrochloride 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.

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 (59°F -86°F) in a dry place and protect from light.

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 years:** Do not use without consulting a doctor

Inactive ingredients

pregelatinized starch, microcrystalline cellulose, maize (corn) starch, povidone, croscarmellose sodium, magnesium stearate, colloidal silicone dioxide, hydroxypropyl methylcellulose, polyethylene glycol.

Questions?

call toll-free **1-800-630-8895**

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

NDC 80513-517-72

Maximum Strength Urinary Pain Relief

99.5 mg Phenazopyridine Hydrochloride

#1 DOCTOR RECOMMENDED OTC INGREDIENT FOR UTI PAIN

TEMPORARY RELIEF OF URINARY PAIN, BURNING & URGENCY

Urinary Analgesic

72 Tablets

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Size and color of tablet may vary.

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.

*This product is not manufactured or distributed by I-Health, Inc., owner of the registered trademark of AZO Urinary Pain Relief® Maximum Strength

Distributed by:

ADVANCED RX LLC,

1942 NE 163rd St North Miami Beach,

FL 33162 U.S.A.

MADE IN USA

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts	Purpose
Active ingredient (in each tablet) Phenazopyridine Hydrochloride 99.5 mg.....Urinary tract analgesic	
Use Relief from urinary pain, burning, urgency and frequently associated with urinary tract infections.	
Warnings Do not exceed recommended dosage. Ask a doctor before use if you have: <ul style="list-style-type: none"> ■ Kidney disease ■ allergies to foods, preservatives or dyes ■ had a hypersensitive reaction to Phenazopyridine Hydrochloride Do not use if you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your physician.	
When using this product <ul style="list-style-type: none"> ■ 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. 	
⚠ 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 .	

PEEL FOR WARNINGS & DIRECTIONS

LIFT HERE

<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ your symptoms last for more than 2 days ■ you suspect you are having an adverse reaction to the medication. <p>■ Long-term administration of phenazopyridine hydrochloride has induced neoplasia in rats (large intestine) and mice (liver). Although no association between phenazopyridine hydrochloride and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted.</p> <p>If pregnant or breast-feeding, ask a health professional before use. A pregnancy test and consultation with a health professional if pregnancy is confirmed is recommended prior to use.</p> <p>Keep out of reach of children. In case of an overdose, get medical help or contact a Poison Control Center right away.</p> <p>Other Information</p> <ul style="list-style-type: none"> ■ 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. 	<p>Directions</p> <ul style="list-style-type: none"> ■ 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. 	<p>Inactive ingredients</p> <p>pregelatinized starch, microcrystalline cellulose, maize (corn) starch, povidone, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, polyethylene glycol</p>	<p>Questions? call toll-free 1-800-630-8895</p> <p><small>Size and color of tablets may vary. *This product is not manufactured or distributed by I-Health, Inc., owner of the registered trademark of AZO Urinary Pain Relief® Maximum Strength.</small></p> <p>Distributed by: ADVANCED RX LLC, 1942 NE 163rd St North Miami Beach, FL 33162 U.S.A.</p>
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phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80513-517
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	99.5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	SP9
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80513-517-72	72 in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2024	

Labeler - Advanced Rx LLC (042795108)

Establishment

Name	Address	ID/FEI	Business Operations
INVAHEALTH INC.		116840615	manufacture(80513-517)

Revised: 5/2024

Advanced Rx LLC