

URO-PAIN MAXIMUM STRENGTH- phenazopyridine hydrochloride tablet **Rising Pharma Holdings, 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.

URO-PAIN Maximum Strength

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

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 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 healthcare professional before use. **A pregnancy test and consultation with a healthcare 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.

Inactive ingredients carnauba wax, croscarmellose sodium, hypromellose,

magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized corn starch. May also contain corn starch.

Other Information

- This product contains Phenazopyridine Hydrochloride, known to the State of California to cause cancer
- 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: Product is sealed within blisters. Do not use if any part of the blister is torn, open or damaged.

Questions or comments? Call 1-844-474-7464

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816
Made in India
Mfg License Code:
RA/Drug/RAJ.-1750

Issued: 09/2023

Packaging

NDC 57237-330-42

URO-PAIN™

Phenazopyridine Hydrochloride Tablets, 99.5 mg

Urinary Tract Pain Relief

- **Relieves Pain, Burning and Urgency**
- **Targets the source of Pain**

Drug Facts (Continued)

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URO-PAIN™

Maximum Strength

Phenazopyridine Hydrochloride Tablets, 99.5 mg

Urinary Tract Pain Relief

- Relieves Pain, Burning and Urgency
- Targets the source of Pain

24 Tablets

Distributed by: Rising Pharma Holdings, Inc., East Brunswick, NJ 08816
Made in India
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RP0068

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 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.	
If pregnant or breastfeeding , ask a healthcare professional before use. A pregnancy test and consultation with a healthcare 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.	
Inactive Ingredients carnauba wax, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized corn starch. May also contain corn starch.	

URO-PAIN MAXIMUM STRENGTH

phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-330
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
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	red (Maroon)	Score	no score
Shape	CAPSULE	Size	9mm
Flavor		Imprint Code	p99
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-330-21	1 in 1 CARTON	12/06/2023	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:57237-330-42	1 in 1 CARTON	12/06/2023	
2		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		12/06/2023	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 12/2023

Rising Pharma Holdings, Inc.