URISTAT ULTRA- phenazopyridine hydrochloride tablet
Medtech Products 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.

Uristat Ultra

URISTAT ® ULTRA

Phenazopyridine Hydrochloride 99.5 mg

Drug Facts

Active ingredient (in each tablet)

Phenazopyridine hydrochloride 99.5 mg

Purpose

Urinary analgesic

Use

fast 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

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
- experience a yellowish tinge of skin or eyes

- experience fevers chills, back pain or bloody urine

If pregnant or breast-feeding,

ask a health care professional before use.

Keep out of reach of children.

In case of an overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- **Adults and children 12 years of age and over:** take 2 tablets 3 times daily with a full glass of water, with or after meals as needed
- **Children under 12 years of age:** consult a doctor.
- **Do not use for more than 2 days (12 tablets) without consulting a doctor**

Other information

- This product may stain contact lenses
- This product can interfere with laboratory tests including urine, glucose (sugar), and ketones test
- Long term administration of phenazopyridine HCl 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
- Store at 20º-25º C (68º-77º F) in a dry place and protect from light.

Inactive ingredients

citric acid, artificial & natural cranberry flavor, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, povidone, pregelatinized starch, silica, starch, and sucralose.

Questions?

1-800-344-7239 Uristat.com

PRINCIPAL DISPLAY PANEL

URISTAT® ULTRA with Cranberry flavored coating

UTI Pain Relief Tablets

Phenazopyridine Hydrochloride 99.5 mg

30 Urinary Pain Relief Tablets

PRINCIPAL DISPLAY PANEL

RISTAT® ULTRA with Cranberry flavored coating

UTI Relief PAK™

Phenazopyridine Hydrochloride 99.5 mg

1 UTI Test Strip and 12 Urinary Pain Relief Tablets

URISTAT ULTRA

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63029-105
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	brown	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor	CRANBERRY	**Imprint Code**	X
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63029-105-12	1 in 1 CARTON	02/15/2018	
1		12 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		
2	NDC:63029-105-30	3 in 1 CARTON	02/15/2018	
2		10 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		02/15/2018	

Labeler - Medtech Products Inc. (122715688)

Revised: 10/2025 Medtech Products Inc.