URISTATUTI RELIEF PAK UTI RELIEF PAK- phenazopyridine hydrochloride tablet
Liberty Pharmaceuticals, 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

Drug Facts

Active ingredient

(in each tablet)

Phenazopyridine hydrochloride 95mg

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

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

corn starch, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, and talc

Questions?

Call **1-800-344-7239** or visit our website at www.Uristat.com

Insight Pharmaceuticals LLC
Tarrytown, NY 10591
A Prestige Brands Company

Repackaged By:

Aidarex Pharmaceuticals, LLC.

Corona, CA 92882

PRINCIPAL DISPLAY PANEL

Phenazopyridine Hydrochloride 95mg

URISTATUTI RELIEF PAK UTI RELIEF PAK

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0440-8065(NDC:63736-961)
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**
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics			
Color	BROWN	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	U
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0440-8065-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2015	
2	NDC:0440-8065-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2015	
3	NDC:0440-8065-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/29/2015	
4	NDC:0440-8065-69	96 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/29/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/29/2015	

Labeler - Liberty Pharmaceuticals, Inc. (012568840)