URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet
Safrel Pharmaceuticals, 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.

PHENAZOPYRIDINE HCL Tablet Maximum Strength

Active ingredient (in each tablet)

Phenazopyridine Hydrochloride 99.5 mg

Purpose

Urinary Tract Analgesic

Keep out of reach of children. In case of an overdose, get medical help or contact poison Control Center right away.

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

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

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 adminitration of phenazopyridine hydrochloride has induced neoplasia in rats (large instestine) andmice (liver). Although no association between phenazopyridine hydrochloride and human enoplasia has beeen reported, adequate epidemiological studies along these lines have not been conducted.

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.**

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.

■ 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

■ 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 room temperature 15°-30°C (59°-86°F) in a dry place and protect from light

■ Adults and children 12 years of age and over: 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

■ **C**hildren under 12: Do not use wihout consulting a doctor

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

call toll-free **1-845-547-2667**

Size and color of tablets may vary.

*This product is not manufactured or distributed by the owner of the registered trademark AZO Urinary Pain Relief®.

Distributed by: Safrel Pharmaceuticals, LLC

Bridgewater, NJ 08807

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

MAXIMUM STRENGTH

Urinary Pain Relief

PHENAZOPYRIDINE HYDROCHLORIDE 99.5 mg

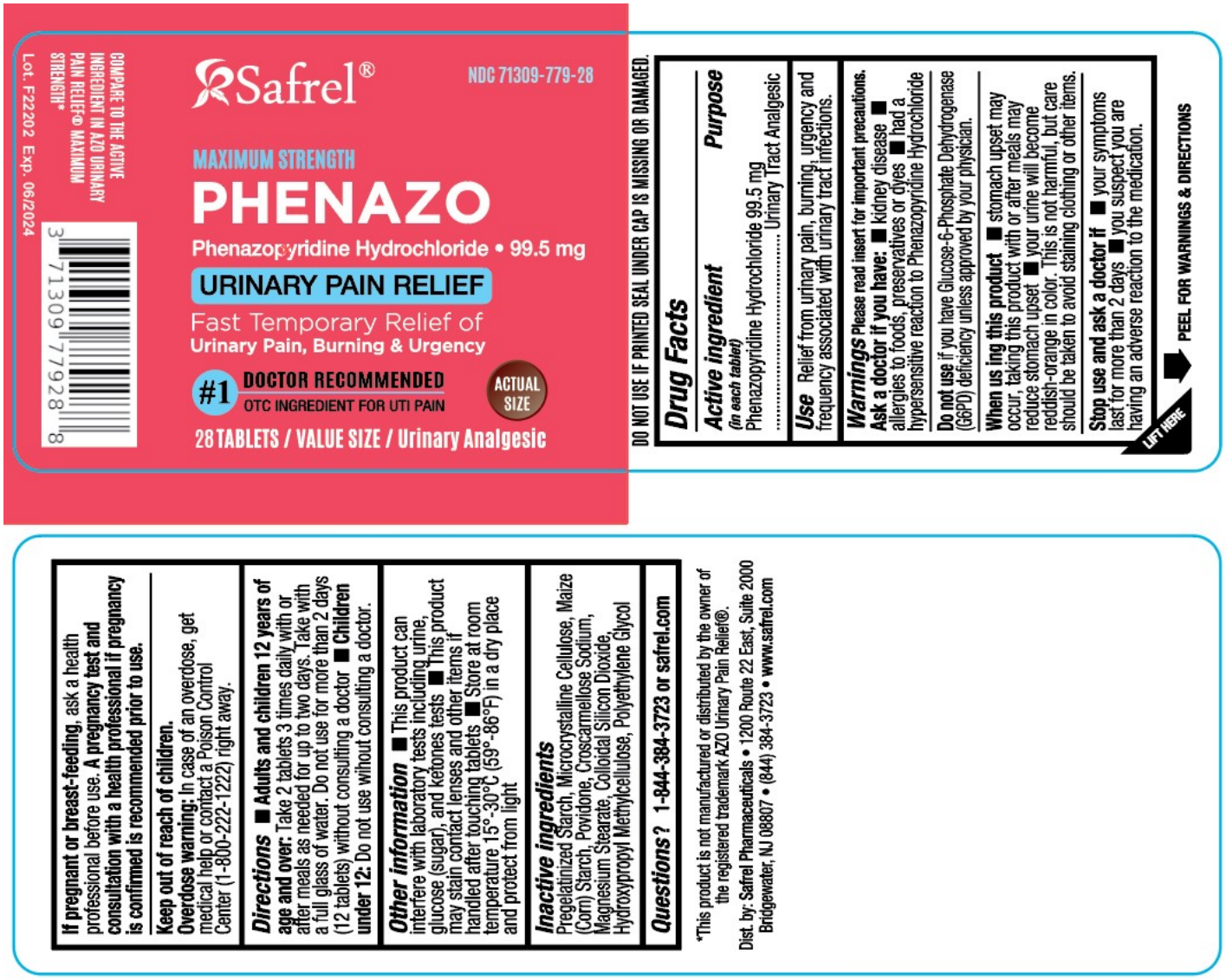
Quickly eases urinary pain, burning & urgency

• More active ingredient for maximum relief

• Provides targeted relief for urinary pain

NDC 71309-779-72 - 72 Count

NDC 71309-779-28- 28Count



URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71309-779
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**
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71309-779-72	72 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2022	
2	NDC:71309-779-28	28 in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/01/2022	

Labeler - Safrel Pharmaceuticals, LLC. (080566287)

Revised: 8/2022 Safrel Pharmaceuticals, LLC.