URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet YYBA CORP

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.

YYBA (as PLD) - WELMATE - URINARY PAIN RELIEF (73581-909)

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.

UseRelief 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 useif 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 HCI 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
- Children 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

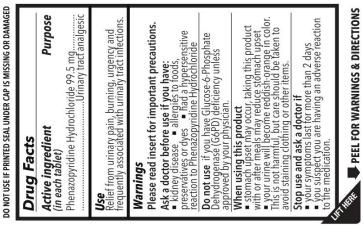
Size and color of tablets may vary.

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

Distributed by: Wellspring

Airmont, NY 10952, USA







URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73581-909

Route of Administration ORAL

Active Ingredient/Active Moiety

Active ingredient/Active Molecy				
Ingredient Name	Basis of Strength	Strength		
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII: K2I09EMI52)	PHENAZ OPYRIDINE 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: M28011HH48)			

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

Packaging

#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73581-909- 72	72 in 1 BOTTLE; Type 0: Not a Combination Product	09/10/2020	



Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
	09/10/2020				
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date			

Labeler - YYBA CORP (006339772)

Revised: 1/2024 YYBA CORP