PHENAZOPYRIDINE HYDROCHLORIDE 97.5MG- phenazopyridine hydrochloride tablet
AMOL PHARMACEUTICALS PRIVATE LIMITED

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 Hydrochloride Tablets 97.5mg

Active ingredient (in each tablet)

Phenazopyridine Hydrochloride 97.5 mg

Purpose

Urinary 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.

Warnings **Pleae 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. **Caution:** Do not use this product 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 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 health professional before use.

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 doctor.

Inactive ingredients microcrystalline cellulose , pregelatinized corn starch, hypromellose, povidone, croscarmellose sodium, polyethylene glycol, carnauba wax and magnesium stearate. May also contain corn starch.

Other information • 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 - 86F) in a dry place and protect from light • Tamper evident: tablets sealed in blisters. Do not use if blister foil is open or damaged.

Packaging

PHENAZOPYRIDINE HYDROCHLORIDE 97.5MG

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63189-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	97.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WQ0SDW1A)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics			
Color	brown (Dark brown)	**Score**	no score
Shape	CAPSULE	**Size**	9mm
Flavor		**Imprint Code**	WX
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63189-002-12	1 in 1 CARTON	03/16/2015	03/31/2021
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63189-002-24	1 in 1 CARTON	03/16/2015	03/31/2021
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		03/16/2015	03/31/2021

Labeler - AMOL PHARMACEUTICALS PRIVATE LIMITED (676245969)

Establishment

Name	Address	ID/FEI	Business Operations
AMOL PHARMACEUTICALS PRIVATE LIMITED		676245969	manufacture(63189-002)