RIGHT REMEDIES MAXIMUM STRENGTH URINARY PAIN RELIEFphenazopyridine hydrochloride tablet Strive 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.

RIGHT REMEDIES Maximum Strength Urinary Pain Relief

Drug Facts

Active ingredient (in each tablet)

Phenazopyridine Hydrochloride 99.5 mg

Purpose

Urinary tract analgesic

Use

Relief from urinary pain, burning, urgency and frequency associated with urinary tract infections. Treatment should not exceed 2 days; see Directions

Warnings

Do not exceed recommended dosage

Do not use if you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your physician.

Ask a doctor before use if you have • kidney disease • allergies to foods, preservatives or dyes • had a hypersensitive reaction to Phenazopyridine Hydrochloride

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 administration of Phenazopyridine HCl has induced neoplasia in rats (large intestine) and mice (liver). Although no association between Phenazopyridine HCl and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted.

If pregnant or breastfeeding, 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 right away.

Directions

• Adults and children 12 years 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 years: Do not use without consulting a doctor

Other information

• 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. • Store at room temperature between 20°C -25°C (68°F-77°F) in a dry place and protect from light.

Inactive ingredients

colloidal silicone dioxide, gum acacia extra pure, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, maize starch, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate.

Questions?

1-888-577-8033 Monday-Friday 8am-4pm EST

Compare to the active ingredient in AZO® Urinary Pain Relief Maximum Strength*
maximum strength UTI pain reliever available without a prescription

Among our over the counter urinary pain relief products

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

READ AND KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Distributed by: Strive Pharmaceuticals, Inc.

East Brunswick, NJ 08816

Product of India

*This product is not manufactured or distributed by -Health Inc., distributor of AZO $^{\otimes}$ Urinary Pain Relief

WARNING: This product can expose you to Phenazopyridine Hydrochloride, which is known to the state of California to cause cancer. For more information, visit

Packaging



DRUG FACTS TABLE

Drug Facts Active ingredient (in each tablet) Purpose Phenazopyridine Hydrochloride 99.5 mg.....Urinary tract analgesic USE Relief from urinary pain, burning, urgency and frequency associated with urinary tract infections. Treatment should not exceed 2 days; see Directions Warnings Do not exceed recommended dosage Do not use if you have Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency unless approved by your physician. Ask a doctor before use if you have ■ kidney disease ■ allergies to foods, preservatives or dyes ■ had a hypersensitive reaction to Phenazopyridine Hydrochloride 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 myour symptoms last for more than 2 days myou suspect you are having an adverse reaction to the medication. Long-term administration of Phenazopyridine HCI has induced neoplasia in rats (large

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RIGHT REMEDIES MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-163
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
PHENAZOPYRIDINE HYDROCHLORIDE (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZ OPYRIDINE HYDROCHLORIDE	99.5 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
ACACIA (UNII: 5C5403N26O)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
STARCH, CORN (UNII: O8232NY3SJ)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)		

Product Characteristics			
Color	brown (maroon)	Score	no score
Shape	OVAL	Size	9mm
Flavor		Imprint Code	S160
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692- 163-39	3 in 1 CARTON	12/01/2023	
1		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		12/01/2023	

Labeler - Strive Pharmaceuticals Inc. (080028013)

Revised: 11/2023 Strive Pharmaceuticals Inc.