

SKOPKO URINARY PAIN RELIEF - phenazopyridine hydrochloride tablet

Skopko

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.

DRUG FACTS

Active Ingredient

Phenazopyridine Hydrochloride 95 mg

Purpose

Urinary Analgesic

Uses

fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.

Warning

Do not exceed recommended dosage

Ask Doctor before use if you have

- kidney disease
- allergies to foods, preservatives or dyes
- had a hypersensitive reaction to Phenazopyridine

When using this product

- 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 professional before use.

Keep out of the reach of children

in case of an overdose, get medical help or contact a Poison Control Center right away.

Directions

■ Adults and children 12 and over: take 2 tablets 3 times daily with a full glass of water, with or after meals as needed

■ **Children under 12:** consult a doctor

■ **Do not use for more than 2 days (12 tablets) without consulting a doctor**

Inactive Ingredients

magnesium stearate, microcrystalline cellulose. May also contain carnauba wax,

croscarmellose sodium, hypromellose, lactose, magnesium silicate, maize starch, pharmaceutical

glaze, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate.



SKOPKO URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-098
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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	7mm
Flavor		Imprint Code	CPC64
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-098-01	1 in 1 CARTON	07/01/2013	
1	NDC:37012-098-50	32 in 1 CELLO PACK; Type 0: Not a Combination Product		
2	NDC:37012-098-30	30 in 1 CELLO PACK; Type 0: Not a Combination Product	07/01/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/01/2013	

Labeler - Skopko (023252638)

Registrant - Reese Pharmaceutical Co (004172052)

Revised: 12/2024

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