

PHENAZOPYRIDINE HYDROCHLORIDE- phenazopyridine hydrochloride tablet
NuCare 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.

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

lactose, magnesium silicate, magnesium stearate, microcrystalline

cellulose, pharmaceutical glaze, and sodium starch glycolate. May also contain: corn starch,

croscarmellose sodium, polyvinylpyrrolidone, pregelatinized starch and silicon dioxide.

 NuCare Pharmaceuticals, Inc.

NDC: 68071-2273-3
Phenazopyridine HCl 95mg
#30 Tablets

See manufacturer's label
for full list of ingredients.

Product #: R1669030

Phenazopyridine HCl 95mg
Lot: 000000 NDC: 68071-2273-03
MFR NDC: 49348-076-44 Exp.: 00-00
Serial# 00000000002

Phenazopyridine HCl 95mg
Lot: 000000 NDC: 68071-2273-03
MFR NDC: 49348-076-44 Exp.: 00-00
Serial# 00000000002

GTIN 00368071227338
Serial# 000000000002
Exp. Date 00-00
LOT#: 000000

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Take _____ every _____ hours
_____ times a day.

68071227303-30-000000-000000

Rev 01/01/19

WARNING: KEEP OUT OF REACH OF CHILDREN

STORE AT CONTROLLED TEMPERATURE 59-86°F.

Packaged By:
NuCare Pharmaceuticals, Inc.
Orange, CA 92867

Distributed by:
McKesson San Francisco, CA 94104

PHENAZOPYRIDINE HYDROCHLORIDE

phenazopyridine hydrochloride tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68071-2273(NDC:49348-076)	
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)				
SHELLAC (UNII: 46N107B71O)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
LACTOSE (UNII: J2B2A4N98G)				
MAGNESIUM SILICATE (UNII: 9B9691B2N9)				
Product Characteristics				
Color	red	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	P95	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-2273-3	1 in 1 CARTON	10/07/2020	
1		30 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		07/01/2013		

Labeler - NuCare Pharmaceuticals,Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	relabel(68071-2273)

Revised: 7/2024

NuCare Pharmaceuticals, Inc.