# CYSTEX MAX UTI PAIN RELIEF- phenazopyridine hydrochloride tablet Clarion Brands, LLC

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# **Drug Facts**

## Active ingredient

Phenazopyridine hydrochloride 99.5 mg

# Purpose

Urinary tract analgesic

**Use** fast relief from urinary pain, burning, urgency and frequency associated with urinary tract infections. Treatment should not exceed 2 days without consulting a doctor; see Directions.

# Warnings

- Do not exceed recommended dosage
- Long-term administration of phenazopyridine hydrochloride 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.

#### Do not use

if you have Glucose-6-Phosphare Dehydrogenase (G6PD) deficiency unless approved by your doctor

#### 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

- do not exceed recommended dosage
- 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.
- do not use for more than 2 days (12 tablets) without consulting a doctor

#### 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. A pregnancy test and consultation with a healthcare professional if pregnancy is confirmed is recommended prior to use

**Keep out of the reach of children**. In case of overdose, get medical help or contact a Poison Control Center right away.

# Directions

Adults and children 12 years of age and older: take 2 tablets 3 times a day with a full glass of water or after meals as needed

- children under 12 years:
- ask a doctor

# Other information

- WARNING: This product contains Phenazopyridine Hydrochloride, known to the state of California to cause cancer.
- 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°F-86°F (15°C-30°C) in a dry place and protect from light

**Tamper evident:** Product is sealed within blisters. Do not use if any part of the blister is torn, open or damaged.

# Inactive ingredients

corn starch, croscarmellose sodium, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinylpyrrolidone, pregelatinized starch, silicon dioxide, sodium starch glycolate, talc, triacetin

# Questions

call **1-844-297-8394** 

# PRINCIPAL DISPLAY PANEL

#### MAX STRENGTH

Cystex® Urinary Health

Phenazopyridine Hydrochloride 99.5 mg

# MAX UTI PAIN RELIEF

# FAST-ACTING UTI PAIN RELIEF

Strongest UTI Pain Relief Available for Fast-Acting Relief of Pain & Burning<sup>\*</sup>

 $\checkmark$  Relief of Pain, Burning, & Urgency

 $\checkmark$  Targets Pain at the Source of the UTI

#### STARTS WORKING

IN AS LITTLE AS 15 MINUTES

Cystex is not intended to replace a doctor's care.

# 24 Tablets

TAMPER EVIDENT: TABLETS SEALED IN BLISTER. DO NOT USE IF BLISTER IS OPENED OR DAMAGED.

1000284

# **REV XX/XX REESECODE**

For more information on Cystex Max Strength UTI Pain Relief or other products, please visit www.cystex.com or call 844-297-8394

Distributed by: Cystex LLC 811 Broad Street, Suite 600 Chattanooga, TN 37402 ©2024 \*without a prescription



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CYSTEX MAX UTI PA					
phenazopyridine hydrochlori	de tablet				
Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:69693-514	
Route of Administration	ORAL				
<b>Active Ingredient/Active</b>	Moiety				
Ingr	edient Name		Basis of St	rength	Strength
Phenazopyridine Hydrochlorid UNII:K2J09EMJ52)	• <b>Hydrochloride</b> (UNII: 0EWG668W17) (Phenazopyridine -		Phenazopyridine Hydrochloride		99.5 mg
Inactive Ingredients					
	Ingredient Name			Sti	rength
Starch, Corn (UNII: 08232NY3SJ)					

Croscarmellose Sodium (UNII: M28OL1HH48)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Lactose, Unspecified Form (UNII: J2B2A4N98G)	
Magnesium Stearate (UNII: 70097M6I30)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Polyethylene Glycol, Unspecified (UNII: 3WJQ0SDW1A)	
Povidone, Unspecified (UNII: FZ989GH94E)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sodium Starch Glycolate Type A (UNII: H8AV0SQX4D)	
Talc (UNII: 7SEV7J4R1U)	
Triacetin (UNII: XHX3C3X673)	

# Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	CYSTEX
Contains			

# Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:69693- 514-24	1 in 1 CARTON	08/02/2024	
1	24 in 1 BLISTER PACK; Type 0: Not a Combination   Product			
Μ	arketing	nformation		
Μ	<b>arketing</b>   Marketing Category	nformation Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

# Labeler - Clarion Brands, LLC (079742703)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Pharbest Pharmaceuticals, Inc.		557054835	manufacture(69693-514)		

Revised: 12/2023

Clarion Brands, LLC