CARE ONE MAXIMUM STRENGTH URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet
American Sales

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 (in each tablet)

Phenazopyridine Hydrochloride 97.5 mg .

Purpose

Urinary Analgesic

Warnings

Do not exceed recommended dosage

Ask doctor before use if you have

■ kidney disease
■ allergies to food, preservatives or dyes
■ had a hypersensitive reaction to phenazopyridine

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 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 reach of children

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

Use

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

Inactive ingredients

Lactose, magnesium silicate, magnesium stearate, microcrystalline cellulose, pharmaceutical glaze, and sodium starch glycolate.

Directions

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

■ children under 12 years: consult a doctor

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

CARE ONE MAXIMUM STRENGTH URINARY PAIN RELIEF
phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-150
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**
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	

Product Characteristics			
Color	red	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	975
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:41520-150-12	1 in 1 CARTON	01/04/2010	
1		12 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		01/04/2010	

Labeler - American Sales (809183973)

Registrant - Reese Pharmaceutical Co (004172052)

Establishment

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(41520-150) , repack(41520-150)

Revised: 1/2019 American Sales