CVS MAXIMUM STRENGTH URINARY PAIN RELIEF- phenazopyridine hydrochloride tablet
CVS PHARMACY 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 (in each tablet)

Phenazopyridine Hydrochloride 99.5 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

CVS Health

UTI Test & Relief Pack

PHENAZOPYRIDINE HYDROCHLORIDE, 99.5 mg

TO MAXIMIZE THE ACCURACY OF THE UTI TEST STRIP, PAIN RELIEF TABLETS SHOULD *NOT* BE TAKEN PRIOR TO TESTING.

UTI Test Strips

STEP 1: Use the Urinary Tract Infection Test Strips to test for infection.

Our UTI Test Strips can help to screen if you have a urinary tract infection. They test for both Leukocytes (white blood cells) and Nitrite in urine to be more reliable.

DIRECTIONS: Simply wet one test strip by holding it in your urine stream for 1–2 seconds. Read results at 1 minute for Nitrite and at 2 minutes for Leukocytes. Match the color of the test strip pads to the color blocks on the foil pouch. Please refer to Package Insert for full directions.

Urinary Pain Relief Tablets

STEP 2: If the UTI Test Strip indicates you have a UTI, follow the instructions below to help temporarily relieve your pain with Urinary Pain Relief Tablets. If the UTI Test Strip indicates you do not have a UTI, DO NOT TAKE the Urinary Pain Relief Tablets. You may save them for future use. For medical advice or questions, please consult a doctor or healthcare professional.

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

Drug Facts

Active ingredient (in each tablet) — **Purpose**

Phenazopyridine Hydrochloride 99.5 mg ..... Urinary Tract Analgesic

Use Fast 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

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 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.

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 1-800-222-1222.

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
- **Do not use for more than 2 days (12 tablets) without consulting a doctor**
- **children under 12 years:** consult a doctor

Other information
- this product may stain contact lenses
- this product can interfere with laboratory tests including urine, glucose (sugar), and ketones tests
- store at room temperature 15°-30°C (59°-86°F) in a dry place and protect from light

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

WARNING: This product can expose you to phenazopyridine hydrochloride, which is known to the state of California to cause cancer. For more information, visit www.P65Warnings.ca.gov

*This product is not manufactured or distributed by DSM IP Assets B.V., owner of the registered trademark AZO Urinary Pain Relief® Maximum Strength.

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PAPER BOX | MULTI-LAYER POUCH | MULTI-LAYER TRAY

100% money back guarantee! CVSCares@cvspharmacy.com

Questions or Comments Call 1-800-321-7178, weekdays, 8am–4pm EST

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Made in the U.S.A. with U.S. and imported ingredients. V-16892

Rev 12/23 CMBDDYS

CVS Health

Compare the active ingredient in the Pain Relief Tablets to the active ingredient in AZO Urinary Pain Relief® Maximum Strength*

NDC 69842-713-14

UTI Test & Relief Pack

PHENAZOPYRIDINE HYDROCHLORIDE, 99.5 mg

2-in-1

2 TEST STRIPS

Fast & easy at-home UTI test

12 TABLETS

Provide targeted relief for urinary pain, burning & urgency

2 TEST STRIPS
12 URINARY RELIEF TABLETS

CVS Health

UTI Test & Relief Pack

PHENAZOPYRIDINE HYDROCHLORIDE, 99.5 mg

CVS MAXIMUM STRENGTH URINARY PAIN RELIEF

phenazopyridine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69842-713
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
LACTOSE (UNII: J2B2A4N98G)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	

Product Characteristics			
Color	brown	**Score**	no score
Shape	OVAL	**Size**	9mm
Flavor		**Imprint Code**	p99
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-713-24	1 in 1 CARTON	09/18/2019	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-713-12	1 in 1 CARTON	09/25/2019	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69842-713-14	1 in 1 CARTON	03/28/2024	
3		12 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2019	

Labeler - CVS PHARMACY INC (062312574)

Registrant - Reese Pharmaceutical Co (004172052)

Revised: 3/2024 CVS PHARMACY INC