

MONISTAT MAINTAIN- phenazopyridine hydrochloride tablet
Insight Pharmaceuticals LLC

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.

Monistat Maintain 63736-020-12

Drug Facts

Active ingredient (in each tablet)

Purpose

Phenazopyridine hydrochloride 99.5 mg.....Urinary analgesic

Use

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

Warnings

Do not exceed recommended dosage.

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
- experience a yellowish tinge of skin or eyes
- experience fevers, chills, back pain or bloody urine

If pregnant or breast feeding,

ask a healthcare professional before use.

Keep out of reach of children.

In case of an overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- **Adults and children 12 years of age and over:** take 2 tablets 3 times daily with a full glass of water, with or after meals as needed.
- **Children under 12 years of age:** consult a doctor.

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

Other information

- This product may stain contact lenses.
- This product can interfere with laboratory tests including urine, glucose (sugar), and ketones tests.
- 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.
- Store at 20°-25° C (68°-77° F) in a dry place and protect from light.

Inactive ingredients

citric acid, artificial & natural cranberry flavor, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, polyethylene glycol, povidone, pregelatinized starch, silica, starch, and sucralose

Questions?

1-877-666-4782 monistat.com

PRINCIPAL DISPLAY PANEL

Maintain™ from the makers of Monistat® A Trusted Leader In Feminine Care (**Logo**)

UTI

2-in-1

TEST + PAIN RELIEF KIT

Phenazopyridine HCl 99.5 mg / Urinary analgesic

with CRANBERRY FLAVORED COATING

2 UTI Test Strips | 12 Urinary Pain Relief Tablets

R53259

Step 1: Test for infection.
Step 2: Temporarily relieve your pain with Maintain™ pain relief tablets from the makers of Monistat®. Use one test strip to help detect if you have a UTI and one to confirm when it's gone.

Directions: Wet 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 strip pads to the color blocks on the foil pouch. See insert inside box for complete instructions.

Drug Facts	
Active ingredient (in each tablet) Phenazopyridine hydrochloride 99.5 mg	Purpose Urinary analgesic
Use: Test relief from urinary pain, burning, urgency and frequency associated with urinary tract infections.	
Warnings Do not exceed recommended dosage.	
Ask a doctor before use if you have: • urinary 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 • you experience a yellowish fringe of skin or eyes • experience fever, chills, back pain or bloody urine	
If pregnant or breast-feeding, ask a healthcare professional before use. Keep out of reach of children. In case of an overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	
Directions: • Adults and children 12 years of age and over: take 2 tablets 3 times daily with a full glass of water, with or after meals as needed. • Children under 12 years of age: consult a doctor. • Do not use for more than 2 days (12 tablets) without consulting a doctor.	
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Questions? 1-877-666-4782 monistat.com

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A Hange Consumer Products Company
80325 Teaneck drug is owned by Inlight Pharmaceuticals LLC
All rights reserved. Test Strip - Made in USA with domestic and imported ingredients. Tablet - Made in India. 14483031021

MAINTAIN™

UTI
2-IN-1

TEST + PAIN RELIEF KIT

Tamper Evident: Do not use if blister unit is broken or torn.

MAINTAIN™

FROM THE MAKERS OF
MONISTAT™
A TRUSTED LEADER IN FEMININE CARE

UTI

2-IN-1

TEST + PAIN RELIEF KIT

PHENAZOPYRIDINE HCL 99.5 MG / URINARY ANALGESIC

with CRANBERRY FLAVORED COATING

MAXIMUM STRENGTH
WITHOUT A PRESCRIPTION

FAST TEMPORARY RELIEF OF:
PAIN, BURNING, URGENCY

+

2 TESTS

1
CONFIRM
UTI

2
ALL
CLEAR

2 UTI Test Strips | 12 Urinary Pain Relief Tablets

MONISTAT MAINTAIN

phenazopyridine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63736-020
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
CITRIC ACID (UNII: 2968PHW8QP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	7mm
Flavor	CRANBERRY	Imprint Code	X
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63736-020-12	1 in 1 CARTON	03/01/2025	
1		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		03/01/2025	

Labeler - Insight Pharmaceuticals LLC (055665422)

Revised: 2/2025

Insight Pharmaceuticals LLC