

**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.*

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**Monistat Maintain 63736-020-12**

**Drug Facts**

**Active ingredient (in each tablet)**

Phenazopyridine hydrochloride 99.5 mg

**Purpose**

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.

WARNING: This product can expose you to chemicals including phenazopyridine hydrochloride, which is known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### **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](http://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

**Drug Facts**

**Active ingredient (in each tablet)** Phenazopyridine hydrochloride 99.5 mg. **Purpose** Urinary analgesic

**Use** Last 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.  
Step 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.  
WARNING: This product can expose you to chemicals including phenazopyridine hydrochloride, which is known to the State of California to cause cancer. For more information go to www.P60Warnings.ca.gov.

**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?** 1-877-666-4762 monistat.com

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Tarrytown, NY 10591, a Prestige Consumer  
Healthcare company  
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Test Strip - Made in USA with domestic and  
imported ingredients. Tablets - Made in India.  
MNH6076102



**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 Nitrate 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.

**MAINTAIN™**  
FROM THE MAKERS OF **MONISTAT™**  
A TRUSTED LEADER IN FEMINE 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**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63736-020
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>PHENAZOPYRIDINE HYDROCHLORIDE</b> (UNII: 0EWG668W17) (PHENAZOPYRIDINE - UNII:K2J09EMJ52)	PHENAZOPYRIDINE HYDROCHLORIDE	99.5 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>CITRIC ACID</b> (UNII: 2968PHW8QP)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M280L1HH48)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

### Product Characteristics

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

### 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)