

URISTAT[®]

Relief PAK[™] TABLETS

Step 1: Test for infection with the URISTAT[™] UTI Test Strip.

Step 2: Temporarily relieve your pain with URISTAT[®] pain relief tablets.

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

URISTAT[®]

Nonprescription temporary pain relief - from the makers of MONISTAT[®] products. URISTAT[®] contains phenazopyridine HCl, the #1 doctor recommended medication used to treat pain or discomfort experienced while urinating.

PRODUCT BENEFITS

- Fast temporary relief of pain, burning, urgency and frequency of urination
- Easy-to-swallow tablet form
- Brought to you by the makers of MONISTAT[®] - the #1 recommendation of doctors and the #1 choice of women for OTC vaginal yeast infection treatments.

HOW TO USE URISTAT[®]

- **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**

WARNINGS

- Do not take if you have previously exhibited hypersensitivity to phenazopyridine HCl or if you have kidney trouble. Remember that advanced age is associated with declining kidney function. Discontinue therapy if you experience a yellowish tinge of the skin or eyes. This may indicate accumulation due to impaired kidney or liver function.
- As with any drug, **if you are pregnant or nursing a baby**, seek the advice of a health professional before using the product.

- If your symptoms persist, are severe, or you experience fever, chills, back pain or bloody urine see your doctor promptly. You may have a serious condition that requires different treatment.
- Phenazopyridine HCl may cause gastrointestinal upset in some people. Take with or after meals to reduce gastric upset and discontinue use if symptoms occur.
- This product may stain soft contact lenses.
- **Keep this and all drugs out of reach of children** and do not administer to children under the age of 12 unless directed by a physician.
- In case of accidental overdose, seek professional assistance or contact a poison control center immediately.
- Carcinogenesis: Long-term administration of phenazopyridine HCl has induced neoplasia in rats (large intestine) and mice (liver). Although no association between phenazopyridine HCl and human neoplasia has been reported, adequate epidemiological studies along these lines have not been conducted.

WHAT IS URINARY DISCOMFORT?

Simply put, urinary discomfort is pain during urination. Often described as a burning sensation, the pain can be severe and may affect the area under the stomach (the abdomen) or the lower back. Most people also feel a strong need to urinate more often or more urgently than usual, even though very little liquid is finally released.

COMMON CAUSES OF A UTI

UTIs typically occur as a result of bacteria entering your urinary system through the urethra. Oftentimes, the bacteria are gastrointestinal and originate in the anus. The bacteria may travel to and multiply in the bladder, and if the infection is not treated, it can spread to the kidneys.

There are certain factors, however, that can make you more susceptible to a UTI. These include being a woman; engaging in sexual activity; and using certain types of birth control, such as diaphragms or spermicidal agents.

HOW TO HELP AVOID UTIs AND URINARY DISCOMFORT

UTIs are not 100% preventable, but you can take some steps to decrease your chances of infection. Some of these precautions include drinking plenty of water, wiping front to back after going to the bathroom, and urinating after sex.

QUESTIONS?

If you have any questions about URISTAT[™] products, please contact Customer Service at 1-800-344-7239 or visit our website at uristat.com. For medical advice or questions, consult a doctor or health professional.

URISTAT[®]

Relief PAK[™] TEST STRIPS

Step 1: Test for infection with the URISTAT[™] UTI Test Strip.
Step 2: Temporarily relieve your pain with URISTAT[®] pain relief tablets.
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INTRODUCTION

URISTAT[™] UTI Test Strips test for white blood cells (Leukocytes) and Nitrite in urine. Detection of these substances in urine aids in the screening of urinary tract infections. The UTI Test Strips are packaged individually in foil pouches. They are for over-the-counter, home use only.

WHEN DO I NEED TO USE UTI TEST STRIPS?

Use the URISTAT[™] UTI Test strips if you have a painful, burning feeling when you urinate, you have to go very often, or only small amounts of urine pass even when you have to go very badly. Seek medical attention if your result indicates there is a possible infection.

WARNINGS AND PRECAUTIONS

- For urine testing only • Follow directions exactly for accurate results
- Keep out of the reach of children • Used strip should be discarded according to local regulations

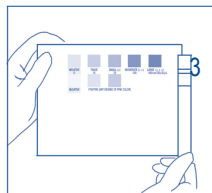
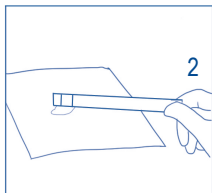
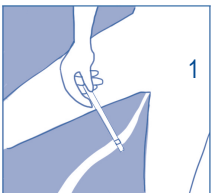
STORAGE AND HANDLING

- Store in a dry place at room temperature between 20°-25°C (68°-77°F) and out of direct sunlight.
- Do not open pouch until ready to use.
- Do not use after expiration date.

DIRECTIONS

Gently wash the genital area with soap and water then rinse well prior to testing.

1. Please read all the information in this package insert carefully before performing the test.
2. Gather the following items:
 - The UTI Test Strip in CLOSED foil pouch
 - Paper towel(s)
 - Watch or Timer
 - A Pen or Pencil (optional)
3. Remove the strip from the foil pouch and use the test immediately. **If the test has been left out of the foil pouch for 20 minutes or more, open a new test strip.**
4. Begin urinating. After some urine has passed, hold the test pads in the urine stream for 1-2 seconds. Make sure both test pads are completely wet. See figure 1 below.
5. Dab the side of the strip on a paper towel to remove excess urine. See figure 2.
6. Lay the test strip with the test pads facing upwards and begin timing.
7. Read test results for Nitrite after 1 minute and for Leukocytes after 2 minutes.
Compare each test area to its corresponding color blocks on the color chart to obtain results. See figure 3. **Be sure to read the test results before 3 minutes have passed. Ignore any color change after 3 minutes.**
8. Record the results with a pen or pencil. Compare them to the table in the Results section.



RESULTS

Hold strip close to color block on foil pouch.

- Compare each test area to its corresponding color blocks on the color chart.
- Match the color of the test pad to the closest color block on the color chart.
- Look at the table to the right to understand what your results mean.

MEANING OF RESULTS

Leukocyte Result	Nitrite Result	Meaning of Your Result
Negative (-)	Negative (-)	No sign of UTI detected. Consult a physician or health professional if you still have symptoms. There are some cases of UTI that the test may not detect.
	Positive (+)	Results suggest a sign of UTI. Consult a physician or health professional immediately.
Trace (+/-)	Negative (-)	Test again the following day using a new strip. If you get another trace Leukocyte result or if you still have symptoms, consult a physician or health professional.
	Positive (+)	Results suggest a sign of UTI. Consult a physician or health professional immediately.
Positive (+, ++, +++)	Negative (-)	Results suggest a sign of UTI. Consult a physician or health professional immediately.
	Positive (+)	Results suggest a sign of UTI. Consult a physician or health professional immediately.

LIMITATION OF USE

The reading of UTI Test Strips results may be affected by several factors.

- Your reading of the results may be affected if you have color vision deficiency (color blindness).
- Dehydration may cause false positive in Nitrite and false negative in Leukocyte.
- Urine with pH \geq 8.0 may cause false negative in Leukocyte.
- You should not be using the UTI Test Strips if you are taking antibiotics.

You may get false and inaccurate results if:

- You have been taking medicine or dietary supplement that may change urine color (such as drugs containing azo dyes (i.e. Pyridium[®], Gantrisin[®], Gantanol[®]), nitrofurantoin (Microdantin[®], Furadantin[®]), riboflavin).
- You are taking Vitamin C or multivitamin.
- You have a UTI caused by bacteria that does not change nitrate to nitrite, or if your diet does not include nitrates.
- When urine has not been held in the bladder for more than 4 hours.
- You are taking drugs containing acetazolamide, potassium citrate, and sodium bicarbonate because your urine pH maybe \geq 8.0.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the URISTAT[™] UTI Test Strips have been determined both in the laboratory and in clinical tests. The UTI Test Strips have been developed to be specific for Leukocyte and Nitrite. They can detect nitrite levels as low as 0.075-0.10 mg/dl and leukocyte levels as low as 15 White Blood Cells/ μ L.

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