



IMPORTANT SAFETY INFORMATION:

Uribel® is not for everyone. You should not take Uribel® if you are allergic to hyoscyamine, methenamine, methylene blue, or phenyl salicylate. Tell your doctor immediately if you develop any of the following symptoms: itching, rash, severe dizziness, swelling, or trouble breathing. These could be signs of a serious allergic reaction.

You should not take more than the prescribed dose of Uribel®. If you experience a rapid pulse, dizziness, or blurred vision, discontinue use immediately. The effects of long-term use of Uribel® are not known.

Tell your doctor about all your medical conditions and all medicines that you take. To make sure this medicine is safe for you, tell your doctor if you have:

- heart disease, including a heart rhythm disorder, congestive heart failure, coronary heart disease or a heart valve disorder;
- glaucoma;
- · an enlarged prostate or bladder obstruction;
- myasthenia gravis;
- an ulcer or obstruction in your stomach or intestines;
- an allergy or hypersensitivity to belladonna or salicylates like NSAIDs and aspirin.

It is not known whether this medication will harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant while using this medication. Some of the ingredients in Uribel® can pass into breast milk and







Paying for Uribel

How Uribel Works

Urinary Tract Disorders

Healthcare Providers



SPEAK UP!

Ask your doctor for relief from urinary tract symptoms.
Ask for Uribel.

Start the conversation >

Uribel is a prescription medicine used to relieve the discomfort, pain, frequent urge to urinate, and cramps/spasms of the urinary tract caused by a urinary tract infection or a diagnostic procedure.

GET URIBEL® FOR AS LITTLE AS \$10

Save up to \$40 on every Uribel prescription.

Get the coupon >

Speaking of symptoms

Create a list of symptoms to show your doctor



Go >

Uribel relieves more than pain When symptoms

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EXPAND ^

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This medicine should not be given to young children or infants. Elderly adults may be more likely to have side effects such as excitement, agitation, drowsiness or confusion from this medication.

This medication may interact with other drug products. Keep a list of all the medicines you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Before taking Uribel®, tell your doctor about all medications you are taking including: products that decrease the amount of acid in the urine (such as antacids, sodium bicarbonate, potassium/sodium citrate, acetazolamide), diuretics (water pills), antimuscarinic medicines use to treat asthma and COPD, and certain gastrointestinal and urinary tract disorders (e.g., overactive bladder), antacids, and drugs to treat diarrhea. If you are taking any of these medications and your doctor prescribes Uribel®, you should take this product at least one hour before or after taking these other medications. You should also tell your doctor if you are taking medications for myasthenia gravis, sulfonamide drugs (including sulfa antibiotics such as sulfamethoxazole), narcotic pain medications, MAO inhibitors, or antifungal medicines. If you are taking certain antifungal drugs (such as ketoconazole), take this product at least 2 hours after the antifungal drug. Taking MAO inhibitors (isocarboxazid, linezolid, moclobemide, phenelzine, procarbazine, rasagiline, selegiline, tranylcypromine) with this medication may cause a serious drug interaction. Ask your doctor when to start or stop taking these medications. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

inability to urinate, dry mouth, nausea, vomiting, shortness of breath or trouble breathing. This medicine can cause your urine and sometimes your stools to turn a bluish color. This effect is harmless and will stop after the medication is discontinued.

Seek immediate medical attention if you notice symptoms of a serious allergic reaction such as itching, rash, severe dizziness,

The most common side effects of Uribel® are rapid heartbeat, flushing, blurred vision, dizziness, drowsiness, difficulty urinating,

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Access information about Uribel

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Are any of these issues holding you back?



It's embarrassing

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I don't want to be a whiner

I think symptoms are inevitable

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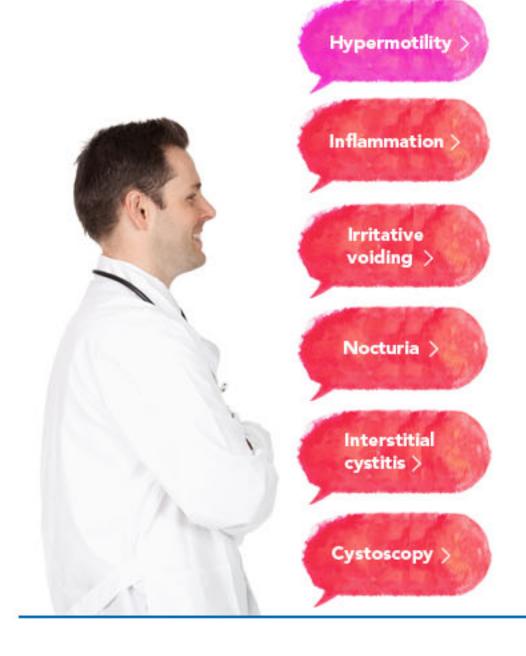




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- Having to go to the bathroom has interrupted an event or outing that I was attending.
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Your doctor can only help you if you are completely open and honest with her or him. If you are experiencing extreme discomfort that is affecting your quality of life, your doctor wants to know that so that he/she can help you fix it. It's OK to ask for help. You have a right to ask for help.

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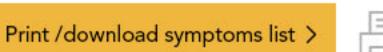
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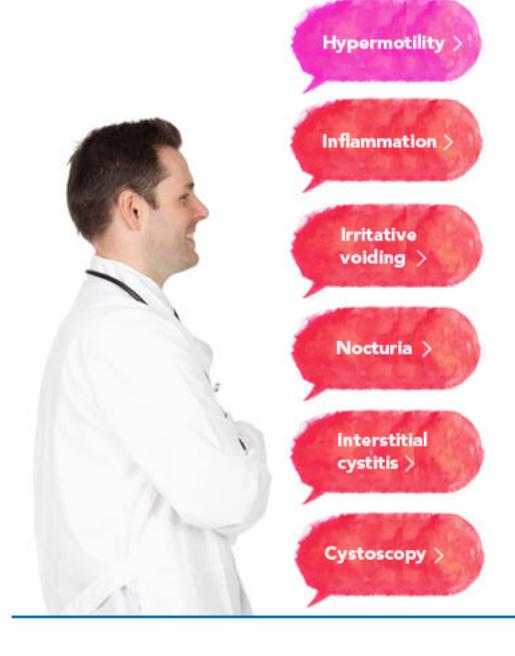




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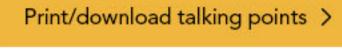
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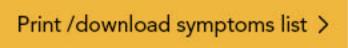
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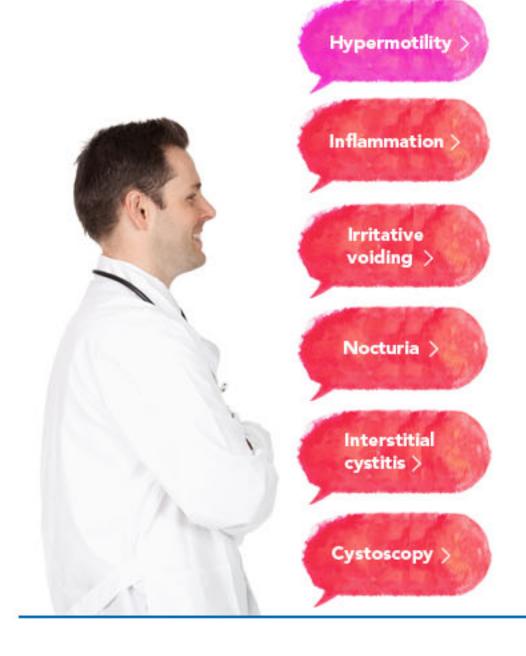


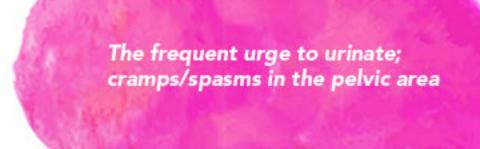


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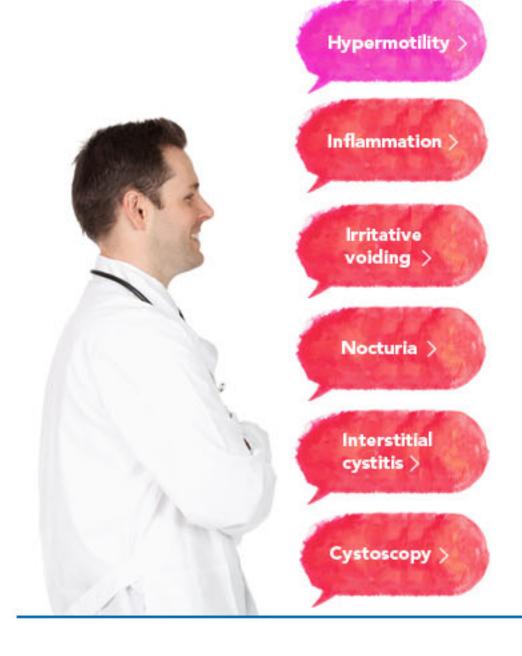




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Doctors can't read your mind. If you don't tell them you are having issues with symptoms, they may conclude that you don't need extra relief. Your relationship with your doctor should be a two-way street.

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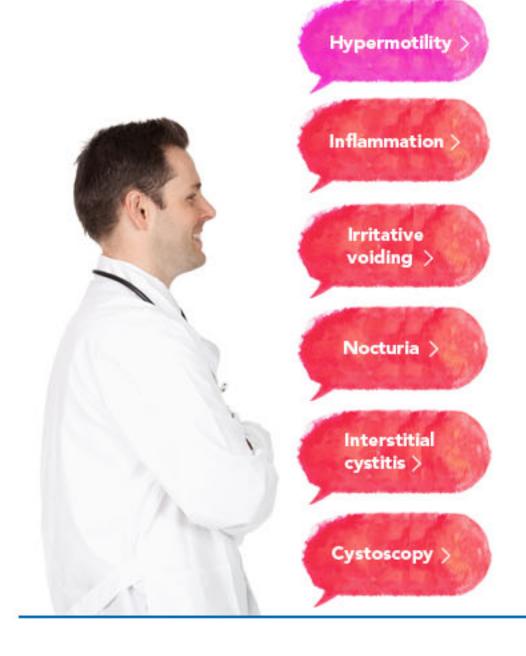




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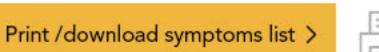
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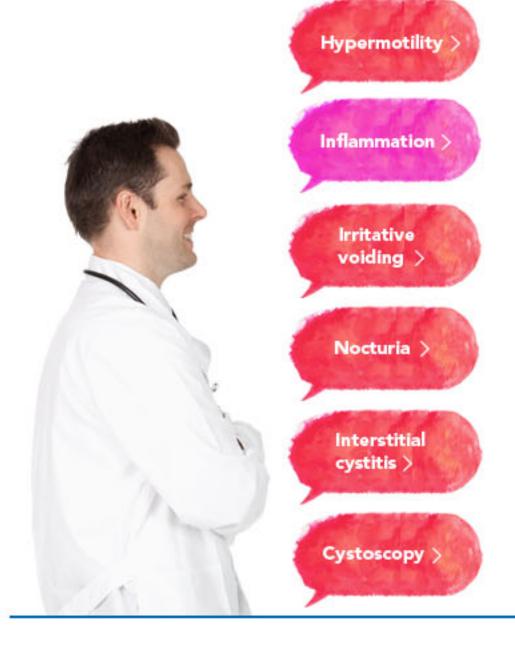




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The tissues lining your urinary tract may become irritated and painful ("inflamed") due to an infection or diagnostic procedure.



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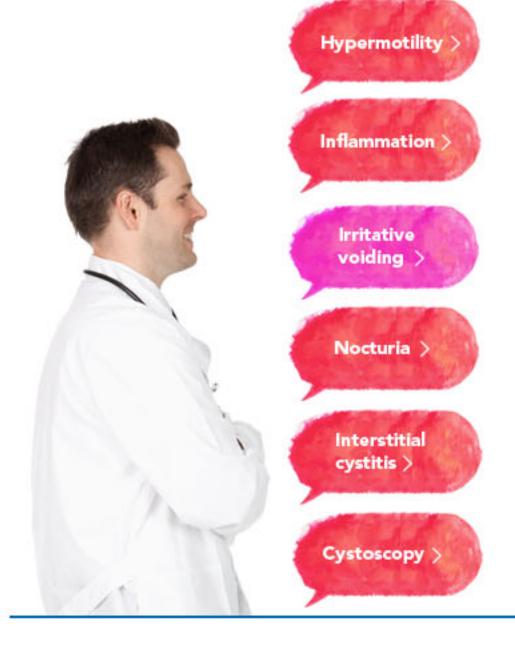




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Urinary tract disorders are a very personal problem, so you may reluctant to talk about the symptoms in any kind of detail. You may want to make your office visit as brief as possible. **Urinary tract disorders are very common and nothing to be ashamed of.**

I don't want to be a whiner

I think symptoms are inevitable

I can tough it out

I just do whatever the doctor says

See how Uribel can help relieve your urinary tract symptoms >

Speaking of urinary tract symptoms

Urinary tract disorders may cause a wide variety of symptoms. Use the checklist below to create a list of all your symptoms that you can then print out and bring to your doctor's visit.

Painful urination (before, during, or after)

Frequent urge to urinate/bladder spasms

Chills, fever,

Repeatedly waking up in the middle of the night to urinate

Pain the the lower back

Pelvic cramps/soreness

Bladder pain and/or pressure Accidents

Fatigue/malaise

Print /download symptoms list >

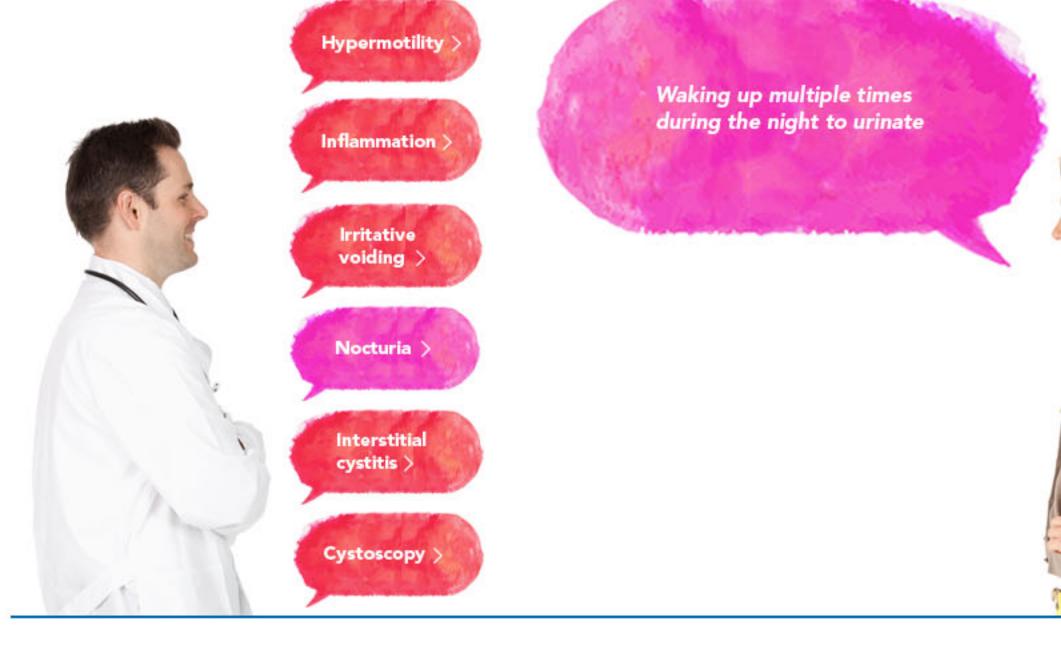




Learn more about urinary tract disorders >

Learn the lingo

These are some medical terms related to urinary tract disorders that you may hear at your doctor's office. Click on each word to read a "translation" of the term into layman's terms.



Tell it like it is

Urinary tract symptoms may be affecting your quality of life. If one or more of these situations has happened to you, it's worth talking to your doctor about.

Work Urinary tract symptoms make it hard to stay in one position for a long period of time, which has limited my ability to get work done. Urinary tract symptoms have caused me to lose sleep, which has affected my job performance. Urinary tract symptoms have caused me to miss work. Family I have missed a family event due to my urinary tract symptoms. I was unable to attend one of my children's activities (sports, music, etc) due to urinary tract symptoms. Urinary tract symptoms have made it harder for me to fulfill family obligations. Recreation Having to go to the bathroom has interrupted an event or outing that I was attending. Worrying about having an accident has prevented me from participating in an activity. Thinking about urinary pain and discomfort has distracted me during an activity.









Paying for Uribel

How Uribel Works

Urinary Tract Disorders

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TALKING TO YOUR DOCTOR

SPEAK UP and ask for relief.

Urinary tract disorders are a very personal medical issue. It's normal to feel reluctant to talk about your symptoms, even with a trusted physician. You may keep quiet or minimize the symptoms you are suffering, but if you need relief, you should feel empowered to let your doctor know.

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Print /download symptoms list >





Learn more about urinary tract disorders >

Learn the lingo

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A condition that causes recurring discomfort or pain in the bladder and the surrounding pelvic region; some of the symptoms of interstitial cystitis resemble urinary tract infections, but medical tests reveal no bacteria and antibiotics are not effective



Tell it like it is

Urinary tract symptoms may be affecting your quality of life. If one or more of these situations has happened to you, it's worth talking to your doctor about.

Work

- Urinary tract symptoms make it hard to stay in one position for a long period of time, which has limited my ability to get work done.
- Urinary tract symptoms have caused me to lose sleep, which has affected my job performance.
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Family

- I have missed a family event due to my urinary tract symptoms.
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Recreation

- Having to go to the bathroom has interrupted an event or outing that I was attending.
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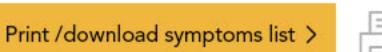
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An examination of the inside of the bladder and urethra using a long, thin instrument with an eyepiece on the external end and a tiny lens and a light on the end



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Paying for Uribel

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PAYING FOR URIBEL

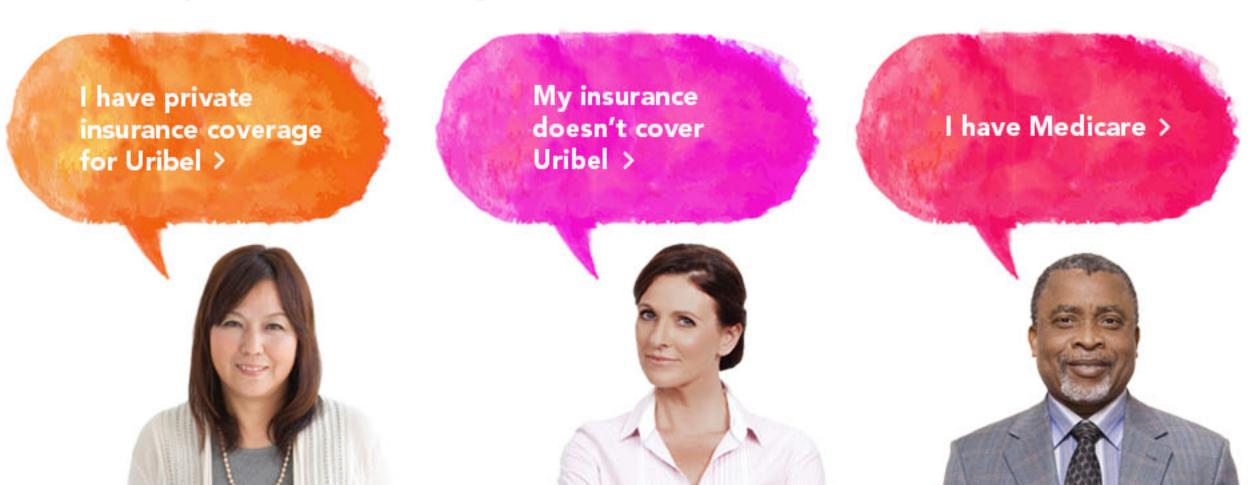
Pay as little as \$10 per prescription for Uribel

 There is no limit on the number of times you may use this coupon

Download and print coupon >



The Uribel coupon is available to everyone



How to use the Uribel coupon

STEP 1: Print out the coupon and bring it to your doctor's office.

STEP 2: Talk to your doctor.

If you have private insurance coverage for Uribel, ask your doctor:

"May I have a full prescription for Uribel?"

If you have Medicare or Medicaid, or you don't have coverage for Uribel under private insurance, ask your doctor:

"May I have a prescription for 20 capsules of Uribel, with each refill also for 20 pills?"

STEP 3: Talk to your pharmacist

"I have private insurance coverage for Uribel. What is my co-payment or coinsurance for Uribel? Is my co-payment more expensive than the full retail price?" (In some cases, if you pay for Uribel out-of-pocket [without using insurance] and use the Uribel coupon, your prescription may be less expensive than it would be if you used insurance.)

"I don't have insurance coverage for Uribel. I'll be paying the full retail price for Uribel."

"I have Medicare (or Medicaid)." I want to pay for Uribel out-of-pocket at the full retail price."

STEP 4: Present the Uribel coupon to your pharmacist

"Here is my Uribel coupon. I'll be using this coupon every time I fill a prescription for Uribel. Thanks!"

Helpful Links



Fingertip Formulary® is a simple-to-use tool that allows you to determine formulary drug status for health plans in your area.

To learn more about different coverage levels/drug tiers, click on "About Formularies" and the tier result after you have selected Uribel and your state.



Learn more about pricing for Uribel at <u>GoodRx.com</u>.



Learn how Uribel treats more than just pain >







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PAYING FOR URIBEL

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Download and print coupon >



The Uribel coupon is available to everyone

If you have private insurance coverage for Uribel

 Use the coupon to offset the cost of your co-payment or coinsurance

If you don't have insurance coverage for Uribel

 Use the coupon to receive a \$40 discount off the retail price of each Uribel prescription

If you have Medicare

- You do not have coverage for Uribel
- Use the coupon to receive a \$40 discount off the retail price of each Uribel prescription
- Medicare patients are entitled to use this coupon if they are paying the full retail cash price for Uribel and do not receive any insurance benefit

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Learn how Uribel treats more than just pain >







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HOW URIBEL WORKS

Uribel treats more than just pain

Uribel is a prescription medicine used to relieve the discomfort, pain, frequent urge to urinate, and cramps/spasms of the urinary tract caused by a urinary tract infection or a diagnostic procedure.

Some urinary medicines contain only 1 ingredient—an analgesic for pain relief. Uribel contains 5 ingredients that work together to treat your symptoms:

- A pain reliever to treat pain and burning sensations when you urinate
- An antispasmodic to help relax the smooth muscle tissue of your urinary tract
- A combination of antiseptic ingredients*

What to expect when taking Uribel

- Take one Uribel capsule 4 times a day; however, please follow your doctor's instructions
- Take each Uribel dose with ample amounts of fluid
- Uribel may be used in conjunction with antibiotic therapies; however, ask your doctor to be sure there are no potential drug interactions
- You should not take more than the recommended dose of Uribel capsules
- Uribel typically causes your urine to turn blue or bluish-green and may also affect the color of your stool. This is a harmless effect



*Uribel does not replace antibiotic therapy prescribed by your doctor.

References

- 1. McPhee JS, Papadakis MA, eds. Current Medical Diagnosis and Treatment. New York, NY: McGraw Hill Medical; 2009:828-838.
- 2. Panzera AK. Interstitial cystitis/painful bladder syndrome. *Urol Nurs.* 2007 Feb;27(1):13-19.





Learn how you can pay as little as \$10 for Uribel >







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How Uribel Works

Urinary Tract Disorders

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URINARY TRACT DISORDERS

The Urinary Tract

The urinary tract is the body's drainage system for removing urine, which is composed of wastes and extra fluid. In order for normal urination to occur, all body parts in the urinary tract need to work together in the correct order.

Common reasons for painful urinary symptoms

Urinary pain and discomfort can have a wide variety of possible causes2:

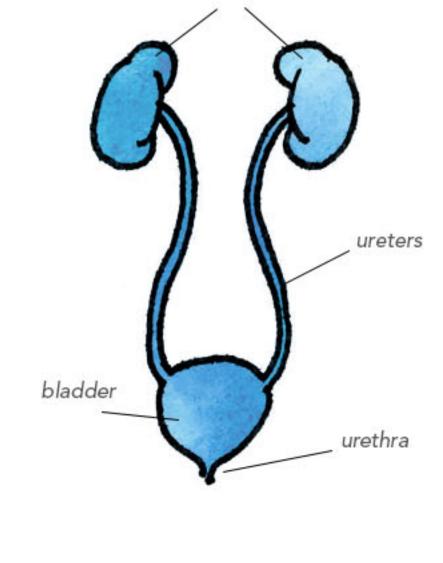
- Urinary tract infections (UTIs)
- Interstitial cystitis
- Diagnostic procedures
- Prostatitis
- Sexually transmitted diseases
- Kidney stones
- Some types of cancer (renal, bladder, prostate, transitional cell, endometrial, vulvar)

UTIs

A UTI is an infection in the urinary tract. Bacteria are the most common cause of UTIs. Normally, bacteria that enter the urinary tract are rapidly removed by the body before they cause symptoms. However, sometimes bacteria overcome the body's natural defenses and cause infection.³

Most UTIs are caused by bacteria that live in the bowel. The bacterium Escherichia coli (E. coli) causes the vast majority of UTIs.³

Urinary tract infections are the second most common type of infection in the body, accounting for about 8.1 million visits to healthcare providers each year. Women are especially prone to UTIs for anatomical reasons. For women, the lifetime risk of having a UTI is greater than 50%. UTIs in men are not as common as in women, but can be serious when they occur.³



kidneys

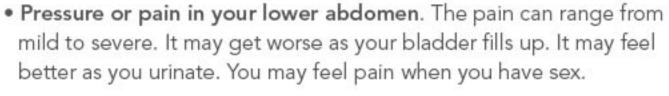


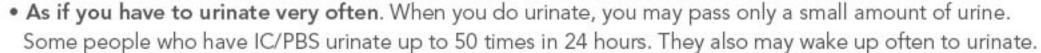
- An infection in the urethra is called urethritis.³
- A bladder infection is called cystitis.³
- Bacteria may travel up the ureters to multiply and infect the kidneys. A kidney infection is called pyelonephritis.³

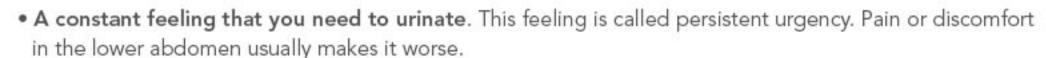


Interstitial cystitis is a medical condition that affects the urinary tract. It can cause bladder pain and a feeling of having to urinate often. Many people with IC/PBS have a hard time sleeping well, working, and enjoying a normal sex life. There's no cure for IC, but there are things you can do to relieve symptoms.⁴

Symptoms vary from person to person and over time. Some people with IC/PBS have only pain or discomfort. Other people may feel the following⁴:







Some of the symptoms of IC resemble those of bacterial infection, but medical tests reveal no organisms in the urine of people with IC. Furthermore, people with IC do not respond to antibiotic therapy. Researchers are working to understand the causes of IC and find effective treatments.⁵



Medical procedures involving special instruments that treat or diagnose urinary conditions can lead to urinary pain, discomfort, and bleeding, and in rare cases may result in a UTI.6 Some examples of urinary diagnostic procedures include:

- Cystometry⁷
 - A small soft tube (called a catheter) is inserted into the urethra until it reaches the bladder. The catheter allows the bladder to be emptied completely (measuring the amount remaining in the bladder after urination known as residual urine) and then to measure the pressures in the bladder.



- Cystoscopy⁶
 - A cystoscopy is an examination of the inside of the bladder and urethra, the tube that carries urine from the bladder to the outside of the body.
- Ureteroscopy⁶
 - A ureteroscope, which is longer and thinner than a cystoscope, is used to see beyond the bladder into the ureters, the tubes that carry urine from the kidneys to the bladder.

References

- National Kidney and Urologic Diseases Information Clearinghouse. The urinary tract and how it works. NIH Publication No. 14–3195. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases; 2013.
- What causes painful urination? Healthline.com. http://www.healthline.com/symptom/painful-urination. Accessed January 15, 2015.
- National Kidney and Urologic Diseases Information Clearinghouse. Urinary tract infections in adults. NIH Publication No. 12–2097. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases; 2011.

4. Interstitial cystitis/painful bladder syndrome. Health Matters. Association of Reproductive Health Professionals; April 2008.

 National Kidney and Urologic Diseases Information Clearinghouse. Interstitial cystitis/painful bladder syndrome. NIH Publication No. 11–3220. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases; 2011.

6. National Kidney and Urologic Diseases Information Clearinghouse. Cystoscopy and ureteroscopy. NIH Publication No.

- 09–4800. Bethesda, MD: National Institute of Diabetes and Digestive and Kidney Diseases; 2009.
- 7. Urology Care Foundation Cystometry. http://www.urologyhealth.org/urology/index.cfm?article=76. Accessed January 15, 2015.









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ANALGESIC

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Urinary Tract Infections

Urinary Tract Disorders

Urinary Diagnostic Procedures

URINARY TRACT DISORDERS

Talking to Your Doctor

Uribel Clincal Profile

Indication

Uribel capsules are indicated for:

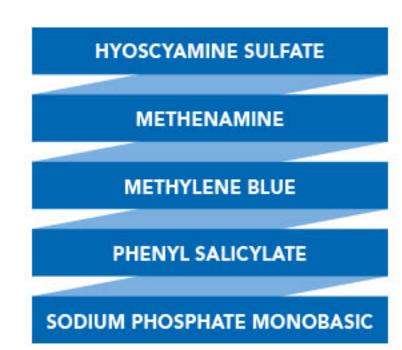
- The treatment of symptoms of irritative voiding.
- The relief of local symptoms, such as inflammation, hypermotility, and pain, which accompany lower urinary tract infections.
- The relief of urinary tract symptoms caused by diagnostic procedures.

Clinical Pharmacology

Uribel relieves urinary tract symptoms with 5 integrated analgesic, antispasmodic, and antiseptic ingredients:

- HYOSCYAMINE SULFATE is a parasympatholytic which relaxes smooth muscles and thus produces an antispasmodic effect.
- METHENAMINE degrades in an acidic urine environment, releasing formaldehyde, which provides bactericidal or bacteriostatic action. Methenamine is freely distributed to body tissue and fluids but is not clinically significant as it does not hydrolyze at pH levels greater than 6.8.
- METHYLENE BLUE possesses weak antiseptic properties.
- PHENYL SALICYLATE releases salicylate, a mild analgesic for pain.
- SODIUM PHOSPHATE MONOBASIC, an acidifier, helps to maintain an acid pH in the urine necessary for the degradation of methenamine.

For more information about Uribel's clinical pharmacology, please see the full <u>Prescribing Information</u>.



Case Studies

Learn how Uribel can help the following patient types:

- Chronic urinary tract conditions
- Urinary tract infections (UTIs)
- Patients undergoing diagnostic procedures









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Chronic Urinary Tract Conditions

Urinary Tract Infections

Urinary Diagnostic Procedures

CHRONIC URINARY TRACT CONDITIONS



Chronic Urinary Tract Conditions

Symptoms 1,2:

- Pelvic pain or pressure (sometimes intense) triggered by a variety of factors, including stress
- Increases as the bladder fills and lessens once the bladder is emptied
- Frequent urination, as often as 10 to 50 times during a 24-hour period

Laura is a working mom who doesn't have time to deal with her urinary tract flare-ups, which recur often.

The urinary pain and pressure can be a constant distraction.

Uribel® Therapy

Uribel contains both antispasmodic and analgesic agents to help relieve local symptoms of:

- Pain
- Inflammation
- Hypermotility

Uribel heltps Laura focus on her busy life, not her symptoms.

The analgesic and antispasmodic ingredients of Uribel help to alleviate the pain and pressure of her symptoms.

References

- Bosch PC, Bosch DC. Treating interstitial cystitis/bladder pain syndrome as a chronic disease. Rev Urol. 2014;16(2):83-87.
- Association of Reproductive Health Professionals. What you need to know: understanding interstitial cystitis/painful bladder syndrome fact sheet. http://www.arhp.org/uploadDocs/understandingicpbsfactsheet.pdf.

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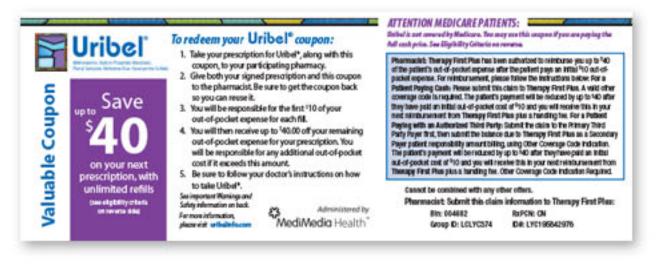
The Uribel coupon is available to everyone. Patients with private insurance can use the Uribel coupon to

offset the cost of a co-payment or coinsurance.

Patients without insurance coverage can use the Uribel coupon to receive a \$40 discount off the retail price of each prescription.

Patients with Medicare can use the Uribel coupon:

- Medicare does not cover Uribel; therefore,
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Clinical Profile Chronic Urinary Tract Conditions

Urinary Tract Infections

Urinary Diagnostic Procedures



Urinary Tract Infections (UTIs)

Symptoms¹:

- A recurring and intense need to urinate
- IA painful, burning feeling in the bladder or urethra during urination

As a public relations maven, Whitney works hard to build hype. But when she has a UTI, her symptoms attract the wrong kind of attention.

Hypermotility and spasms have Whitney running for cover.

Uribel® Therapy

- Hyoscyamine—an antispasmodic agent that helps relax smooth muscle tissue to relieve urinary pressure and spasms
- Phenyl salicylate—an analgesic agent that relieves pain
- A combination of antiseptic ingredients*

Whitney takes Uribel because it treats more than just pain.

It contains an antispasmodic to help alleviate the spasms and hypermotility typically associated with urinary tract disorders.

*Uribel does not replace antibiotic therapy prescribed by your doctor.

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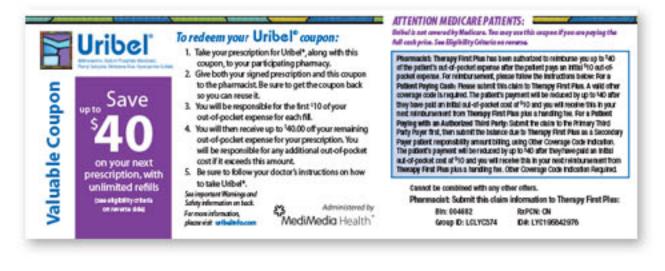
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Clinical Profile Chronic Urinary Tract Conditions

Urinary Tract Infections

Urinary Diagnostic Procedures

University DIAGNOSTIC PROCEDURES

Univer

Urinary Diagnostic Procedures

 Urinary diagnostic procedures, such as cystoscopy, can sometimes result in urinary tract symptoms¹

The last time Frank had a cystoscopy, he developed pain and spasms that kept him uncomfortable all night.

This time around, Frank wants to make sure he has symptom relief available just in case.

Uribel® Therapy

Unlike single-agent analgesics, Uribel contains ingredients that can help to alleviate urinary tract symptoms:

- The antispasmodic agent hyoscyamine, which helps relax smooth muscle tissue to relieve urinary pressure and spasms
- The analgesic agent phenyl salicylate to relieve pain and inflammation

Frank started taking Uribel the day of his cystoscopy to help control possible discomfort symptoms.

The procedure was uncomfortable, but he had the peace of mind that came from knowing that Uribel would help to provide relief.

Reference

Hankel S. Bacterial urinary tract infections.
 The Merck Manual Professional Edition.
 http://www.merck.com/mmpe/sec17/ch231/ch231b.html.
 Accessed December 10, 2014.



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