

UTA

Urinary Tract Antiseptic Capsules



Rapid Relief
When It Counts



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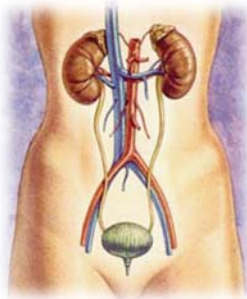
Indications:



UTA Capsules are indicated for:

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

Manage Discomfort:



UTA Capsules may be used to manage discomfort and reduce symptoms associated with such procedures as:

- Catheter use
- Pre and post-laproscopy
- Endometrial biopsy
- Post-Caesarean section
- Honeymoon cystitis

Effective Formula



- METHENAMINE 120 mg**
In presence of acid urine, hydrolyzes to formaldehyde therefore providing antiseptic activity.
- SODIUM PHOSPHATE MONOBASIC 40.8 mg**
An acidifier necessary for breakdown of methenamine into formaldehyde.
- PHENYL SALICYLATE 36 mg**
Has mild analgesic & antiseptic activities.
- METHYLENE BLUE 10 mg**
Turns urine blue and not shocking red or orange. Has antiseptic properties. Encapsulation minimizes the risk of staining.
- HYOSCYAMINE SULFATE 0.12 mg**
Relaxes smooth muscles therefore reducing spasms.

UTA CAPSULES contain inactive ingredients: Dicalcium Phosphate, Gelatin, Microcrystalline Cellulose, Magnesium Stearate, Stearic Acid, Silica, FD&C Blue #1 Lake, D&C Red # 28 Lake and FD&C Red # 940 Lake.

Dosing & Administration



- ADULTS**
One capsule orally 4 times per day followed by liberal fluid intake.
- CHILDREN - Above 6 years of age**
Dosage must be individualized by physician. Not recommended for use in children six years of age or younger.

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Patient Advantages

UTA Capsules have a clear advantage. It's easy to see when you look at what UTA Capsules have to offer your patients.



- Easy to swallow
- Encapsulated
- Will not stain hands, teeth or clothing
- Sugar-free, suitable for diabetics
- Fast relief, often within 30 minutes
- Ease spasm
- Alleviate pain and irritation
- Economically priced
- Blue urine indicator



UTA In Action



"After the birth of my baby, my doctor prescribed UTA caps to help with the voiding discomfort I was experiencing. UTA caps quickly restored comfort so that I was able to focus on my new baby."

Jessica - Home Maker



"With my recurrent urinary tract infections, I was so glad to find UTA caps! They take care of the pain and burning fast, are easy to swallow, and don't stain."

Patricia - Attorney



"The constant dull ache I experienced with prostatitis was quickly relieved by the UTA caps my doctor prescribed. They gave me greater urinary comfort and I didn't have to miss a lesson."

Robert - Jr. League Tennis Coach



"Many of my patients with severe irritative bladder symptoms obtain significantly better relief with UTA caps than with similar medications."

Greg - MD, Community Hospital



UTA CAPSULES URINARY ANTISEPTIC

Rx Only

DESCRIPTION

UTA CAPSULES for oral administration.

Each capsule contains:

Methenamine 120 mg

Sodium Phosphate Monobasic 40.8 mg

Phenyl Salicylate 36 mg

Methylene Blue 10 mg

Hyoscyamine Sulfate 0.12 mg

HYOSCYAMINE SULFATE is an alkaloid of belladonna. Exists as a white crystalline powder. Its solutions are alkaline to litmus. Affected by light. It is slightly soluble in water; freely soluble in alcohol; sparingly soluble in ether.

METHENAMINE (hexamethyleneteramine) exists as colorless, lustrous crystals or white crystalline powder. Its solutions are alkaline to litmus. Freely soluble in water; soluble in alcohol and in chloroform.

METHYLENE BLUE (methylthionine chloride) exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

PHENYL SALICYLATE exists as white crystals with a melting point of 40°- 43° C. It is very slightly soluble in water; freely soluble in alcohol.

SODIUM PHOSPHATE MONOBASIC exists as a white powder. It is freely soluble in water and practically insoluble in alcohol.

UTA CAPSULES contain inactive ingredients: Dicalcium Phosphate, Gelatin, Microcrystalline Cellulose, Magnesium Stearate, Stearic Acid, Silica, FD&C Blue #1 Lake, D&C Red # 28 Lake and FD&C Red #40 Lake.

CLINICAL PHARMACOLOGY

HYOSCYAMINE is a parasympatholytic, which relaxes smooth muscles and thus produces an antispasmodic effect. It is well absorbed from the gastrointestinal tract and is rapidly distributed throughout body tissues. Most is excreted in the urine within 12 hours, 13% to 50% being unchanged. Its biotransformation is hepatic. Its protein binding is moderate.

METHENAMINE degrades in an acidic urine environment releasing formaldehyde which provides bactericidal or bacteriostatic action. It is well absorbed from the gastrointestinal tract. 70%-90% reaches the urine unchanged at which point it is hydrolyzed if the urine is acidic. Within 24 hours it is almost completely (90%) excreted; of this at pH 5, approximately 20% is formaldehyde. Protein binding - some formaldehyde is bound to substances in the urine and surrounding tissues. Methenamine is freely distributed to body tissue and fluids but is not clinically significant as it does not hydrolyze at pH greater than 6.8.

METHYLENE BLUE possesses weak antiseptic properties. It is well absorbed by the gastrointestinal tract and is rapidly reduced to leukomethylene blue which is stabilized in some combination form in the urine. 75% is excreted unchanged.

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.

INDICATIONS AND USAGE

UTA CAPSULES indicated for the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as inflammation, hypermotility, and pain, which accompany lower urinary tract infections. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.

CONTRAINDICATIONS Hypersensitivity to any of the ingredients is possible. Risk-benefit should be carefully considered when the following medical problems exist: cardiac disease (especially cardiac arrhythmias, congestive heart failure, coronary heart disease, mitral stenosis); gastrointestinal tract obstructive disease; glaucoma; myasthenia gravis; acute urinary retention may be precipitated in obstructive uropathy (such as bladder neck obstruction due to prostatic hypertrophy)

WARNINGS

Do not exceed recommended dosage. If rapid pulse, dizziness, or blurring of vision occurs discontinue use immediately.

PRECAUTIONS

Cross sensitivity and/or related problems - patients intolerant of belladonna alkaloids or salicylates may be intolerant of this medication also. Delay in gastric emptying could complicate the management of gastric ulcers.

Pregnancy/Reproduction (FDA Pregnancy Category C) - Hyoscyamine and methenamine cross the placenta. Studies concerning the effect of hyoscyamine and methenamine on pregnancy and reproduction have not been done in animals or humans. Thus, it is not known whether UTA CAPSULES cause fetal harm when administered to a pregnant woman or affect reproduction capacity. UTA CAPSULES should be given to a pregnant woman with caution and only if clearly needed.

Breast feeding - problems in humans have not been documented; however, methenamine and traces of hyoscyamine are excreted in breast milk. Accordingly, UTA CAPSULES should be given to a nursing mother with caution and only if clearly needed.

Prolonged use - there have been no studies to establish the safety of prolonged use in humans. No known long-term animal studies have been performed to evaluate carcinogenic potential.

Pediatric - infants and young children are especially susceptible to the toxic effect of the belladonna alkaloids.

Geriatric - use with caution in elderly patients as they may respond to usual doses of hyoscyamine with excitement, agitation, drowsiness, or confusion.

Drug interactions - because of this product's effect on gastrointestinal motility and gastric emptying, it may decrease the absorption of other oral medications during concurrent use such as: urinary alkalinizers; thiazide diuretics (may cause the urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde); antimuscarinics (concurrent use may intensify antimuscarinic effects of hyoscyamine because of secondary antimuscarinic activities of these medications); antacids/ antidiarrheals (may reduce absorption of hyoscyamine, concurrent use with antacids may cause urine to become alkaline reducing effectiveness of methenamine by inhibiting its conversion to formaldehyde). Doses of these medications should be spaced 1 hour apart from doses of hyoscyamine; antimyasthenics (concurrent use with hyoscyamine may further reduce intestinal motility); ketoconazole (patients should be advised to take this combination at least 2 hours after ketoconazole); monoamine oxidase (MAO) inhibitors (concurrent use may intensify antimuscarinic side effects), opioid (narcotic analgesics may result in increased risk of severe constipation); sulfonamides (these drugs may precipitate with formaldehyde in the urine, increasing the danger of crystalluria). Patients should be advised that the urine may become blue to blue-green and the feces may be discolored as a result of the excretion of methylene blue.

ADVERSE REACTIONS

Cardiovascular - rapid pulse, flushing

Central Nervous System - blurred vision, dizziness

Respiratory - shortness of breath or trouble breathing

Genitourinary - difficult micturition, acute urinary retention

Gastrointestinal - dry mouth, nausea/vomiting

DRUG ABUSE AND DEPENDENCE

A dependence on the use of UTA CAPSULES has not been reported and due to the nature of its ingredients, abuse of UTA CAPSULES is not expected.

OVERDOSAGE

Emesis or gastric lavage. Slow intravenous administration of physostigmine in doses of 1 to 4 mg (0.5 to 1 mg in children) repeated as needed in one to two hours to reverse severe antimuscarinic symptoms. Administration of small doses of diazepam to control excitement and seizures. Artificial respiration with oxygen if needed for respiratory depression. Adequate hydration. Symptomatic treatment as necessary.

DOSAGE AND ADMINISTRATION

Adults - one tablet orally 4 times per day followed by liberal fluid intake. **Older children** - Dosage must be individualized by physician. Not recommended for use in children six years of age or younger.

HOW SUPPLIED UTA Capsules are blue/blue capsules imprinted "646" NDC 45985-646-01 Bottles of 100 capsules

STORAGE

Dispense in a tight, light-resistant container as defined in the USP. Store at controlled room temperature 20° - 25° C (68° - 77° F) with allowable excursions 15° - 30° C (59° - 86° F). Keep container tightly closed.

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Fast Acting

Relieves Pain

Non-Staining

Economically Priced

**No "Orange Book"
Therapeutic Equivalent**

Beware of UTA Caps Copy Cats! 



STEWART-JACKSON PHARMACAL

4587 Damascus Road • Memphis, TN 38118 • ph: 800.367.1395 • fx: 901.362.9102
www.sjpharmacal.com