

Utira™-C Tablets

NDC 63717-513-01

Rx Only

DESCRIPTION:

Each tablet for oral administration contains:

Hyoscyamine Sulfate	0.12 mg
Methenamine	81.6 mg
Phenyl Salicylate	36.2 mg
Sodium Phosphate Monobasic	40.8 mg
Methylene Blue	10.8 mg

Other Ingredients: Calcium Sulfate, Carnauba Wax, D & C Red #27 Lake, Dicalcium Phosphate, FD&C Blue #1 Lake, Gelatin, Hypromellose, Kaolin, Magnesium Silicate, Magnesium Stearate, Microcrystalline Cellulose, Mineral Oil, Pharmaceutical Glaze, Polyethylene Glycol, Polyvinylpyrrolidone, Sugar and Titanium Dioxide. Hyoscyamine Sulfate. [101-31-5] [3(s)-endo]- α (Hydroxymethyl) benzeneacetic acid 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester; 1 α H,5 α Htropan-3 α -ol(-)-tropate (ester);3 α -tropanylS(-)-tropate; l-tropic acid ester with tropine; l-tropine tropate. 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. [100-97-0] 1,3,5,7-Tetraazatricyclo [3.3.1.1^{3,7}] decane; hexamethylenetetramine; HMT; HMTA; hexamine; 1,3,5,7-tetraazaadamantane hexamethylenimine; Uritone; Urotropin. C₆H₁₂N₄; mol wt 140.19; C 51.40%, H 8.63%, N 39.96%.

Methenamine (hexamethylenetetramine) 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.

Phenyl Salicylate. [118-55-8] 2-Hydroxybenzoic acid phenyl ester; Salol. C₁₃H₁₀O₃; mol wt 214.22, C 72.89%, H 4.70%, O 22.41%. Made by the action of phosphorus oxy-chloride on a mixture of phenol and salicylic acid. Phenyl Salicylate exists as white crystals with a melting point of 40-43° C. It is very slightly soluble in water and freely soluble in alcohol.

Sodium Phosphate Monobasic. [7558-80-7] Sodium biphosphate; sodium dihydrogen phosphate; acid sodium phosphate; monosodium orthophosphate; primary sodium phosphate; [H₂NaO₄P:] mol wt 119.98. H 1.68%, Na 19.16%, O 53.34%, P 25.82%. Monohydrate, white, odorless slightly deliquesce crystals or granules. At 100° loses all its water; when ignited it converts to metaphosphate. It is freely soluble in water and practically insoluble in alcohol. The aq soln is acid. PH of 0.1 molar aq soln at 25°: 4.5.

Methylene Blue. [61-73-4] 3,7-bis(dimethylamino) phenothiazin-5-ium chloride; C.I. Basic Blue 9; methylthioninium chloride; tetramethylthionine chloride; 3,7-bis(dimethylamino) phenazathionium chloride.

Methylene Blue (Methylthionine chloride) exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

CLINICAL PHARMACOLOGY:

Hyoscyamine Sulfate 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% to 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.

Phenyl Salicylate releases salicylate, a mild analgesic for pain. 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. Sodium Phosphate Monobasic, an acidifier, helps to maintain an acid pH in the urine necessary for the degradation of methenamine.

INDICATIONS AND USAGE:

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. Risk benefits 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: Teratogenic Effects. Pregnancy Category C – Hyoscyamine Sulfate and Methenamine cross the placenta. Studies have not been done in animals or humans. It is not known whether Utira™-C Tablets cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Utira™-C Tablets should be given to a pregnant woman only if clearly needed.

Nursing Mothers – Problems in humans have not been documented, however, Methenamine and traces of Hyoscyamine Sulfate are excreted in breast milk. Accordingly, Utira™-C Tablets should be given to a nursing woman 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 Use – Infants and young children are especially susceptible to the toxic effect of the belladonna alkaloids.

Geriatric Use – Use with caution in elderly patients as they may respond to usual doses of Hyoscyamine Sulfate 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 alkalizers; 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 Sulfate because of secondary antimuscarinic activities of these medications); antacids/antidiarrheals (may reduce absorption of Hyoscyamine Sulfate, 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 Sulfate; antimyasthenics (concurrent use with Hyoscyamine Sulfate 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 – difficulty micturition, acute urinary retention

Gastrointestinal – dry mouth, nausea/vomiting

DRUG ABUSE AND DEPENDENCE:

A dependence on the use of Utira™-C has not been reported and due to the nature of its ingredients, abuse of Utira™-C is not expected.

OVERDOSAGE:

By exceeding the recommended dosage of Utira™-C, symptomology related to the overdose of its individual active ingredients may be expected as follows:

Hyoscyamine Sulfate: Symptoms associated with an overdose of Utira™-C, will most probably be manifested in the symptoms related to overdose of the alkaloid Hyoscyamine Sulfate. Such symptoms as dryness of mucous membranes; dilation of pupils, hot, dry, flushed skin; hyperpyrexia; tachycardia; palpitations; elevated blood pressure; coma; circulatory collapse and death from respiratory failure can occur due to overdose of these alkaloids.

Methenamine: If large amounts of the drug (2-8 g daily) are used over extended periods (3-4 weeks), bladder and gastrointestinal irritation, painful and frequent micturition, albuminuria and gross hematuria may be expected.

Methylene Blue: Symptoms of Methylene Blue overdose associated with the overdose of Utira™-C are not expected to be discernible from those associated with other active ingredients in Utira™-C.

Phenyl Salicylate: Symptoms of Phenyl Salicylate overdose include burning pain in throat and mouth, white necrotic lesions in the mouth, abdominal pain, vomiting, bloody diarrhea, pallor, sweating, weakness, headache, dizziness and tinnitus. The symptoms, however, are not expected to be discernible from those associated with the other active ingredients in Utira™-C.

Sodium Phosphate Monobasic: Symptoms of Sodium Biphosphate overdose may include diarrhea, dehydration, and electrolyte imbalances.

Treatment: 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 6 years of age or younger.

HOW SUPPLIED:

Utira™-C is an oval, purple tablet imprinted with “HAW 513” on one side, available in bottles of 100 tablets, NDC 63717-513-01, and samples of 20 tablets, NDC 63717-513-99.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

STORAGE:

Preserve and dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure. Store at room temperature, USP.

Manufactured for:
Hawthorn Pharmaceuticals
Madison, MS 39110