URIBEL- methenamine, sodium phosphate, monobasic, monohydrate, phenyl salicylate, methylene blue, and hyoscyamine sulfate capsule
Mission Pharmacal Company

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.

Uribel ®

Rx Only
100 Capsules

DESCRIPTION

Uribel ™ capsules for oral administration

Each capsule contains:	
Methenamine	118 mg
Sodium Phosphate Monobasic	40.8 mg
Phenyl Salicylate	36 mg
Methylene Blue	10 mg
Hyoscyamine Sulfate	0.12 mg

HYOSCYAMINE SULFATE. [620-61-1] [3(S)- *endo*]-α-(Hydroxymethyl)-benzeneacetic acid 8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester sulfate(2:1)(salt); 1αH,5αH-tropan-3α-ol(-)-tropate (ester) sulfate(2:1)(salt); 3α-tropanyl S-(-)-tropate; I-tropic acid ester with tropine; I-tropine tropate. $C_{34}H_{48}N_2O_{10}S$. 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 hexamethylenemine; Uritone; Urotropin. $C_6H_{12}N_4$; 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.

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. $C_{16}H_{18}ClN_3S$; mol wt 319.85, C 60.08%, H 5.67%, Cl 11.08%, N 13.14%, S 10.03%. Methylene Blue (Methylthionine chloride) exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol.

PHENYL SALICYLATE. [118-55-8] 2-Hydroxybenzoic acid phenyl ester; Salol. $C_{13}H_{10}O_3$; mol wt 214.22, C 72.89%, H 4.71%, 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 41°-43° C. It is very slightly soluble in water and freely soluble in alcohol.

SODIUM PHOSPHATE MONOBASIC. [7558-80-7] Phosphoric acid sodium salt (1:1); Sodium biphosphate; sodium dihydrogen phosphate; acid sodium phosphate; monosodium orthophosphate; primary sodium phosphate; H_2NaO_4P; 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° C loses all its water; when ignited it converts to metaphosphate. It is freely soluble in water and practically insoluble in alcohol. The aqueous solution is acid. pH of 0.1 molar aqueous solution at 25° C: 4.5.

Uribel ©capsules contain inactive ingredients: Dicalcium Phosphate, FD&C Blue #1, FD&C Red #3, Gelatin, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Propylene Glycol, Shellac, Silicon Dioxide, Sodium Hydroxide, Stearic Acid, and Titanium Dioxide.

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 the 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 a pH of 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 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

Uribel ©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 benefits should be carefully considered when the following medical problems exist: cardiac disease (especially cardiac arrhythmias, congestive heart failure, coronary heart disease, and 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 Uribel capsules cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Uribel capsules should be given to a pregnant woman 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, Uribel 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

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

ADVERSE REACTIONS

Cardiovascular: rapid heartbeat, flushing

Central Nervous System: blurred vision, dizziness, drowsiness

Genitourinary: difficulty micturition, acute urinary retention

Gastrointestinal: dry mouth, nausea and vomiting

Respiratory: shortness of breath or trouble breathing

Serious allergic reactions to this drug are rare. Seek immediate medical attention if you notice symptoms of a serious allergic reaction, including itching, rash, severe dizziness, swelling or trouble breathing.

This medication can cause urine and sometimes stools to turn blue to blue-green. This effect is harmless and will subside after medication is stopped.

**Call your doctor or physician for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS,
contact Mission Pharmacal at 1-800-298-1087 or FDA at 1-800-FDA-1088, www.fda.gov/medwatch.**

Drug interactions

As a result of hyoscyamine's effects on gastrointestinal motility and gastric emptying, absorption of other oral medications may be decreased during concurrent use with this combination medication. Methylene blue inhibits a range of CYP isozymes in vitro, including 1A2, 2B6, 2C8, 2C9, 2C19, 2D6 and 3A4/5. This interaction could be more pronounced with narrow therapeutic index drugs that are metabolized by one of these enzymes (e.g., digoxin, warfarin, phenytoin, alfentanil, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus and tacrolimus). However, the clinical relevance of these in vitro interactions is unknown.

DRUG ABUSE AND DEPENDENCE

A dependence on the use of **Uribel ©capsules** has not been reported and due to the nature of its ingredients, abuse of **Uribel ©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.

If overdose is suspected, contact your local poison center or emergency room immediately. US residents can contact the US National Poison Hotline at 1-800-222-1222.

DOSAGE AND ADMINISTRATION

Adults

one capsule 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

Uribel capsules are purple/purple capsules imprinted with “S 111”.
NDC 0178-0740-01, bottle of 100 capsules.

STORAGE

Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

Store at controlled room temperature 15°-30°C (59°- 86°F).

Keep in a cool, dry place.
Keep container tightly closed.

WARNING: Keep this and all drugs out of reach of children.

Rx Only

Distributed by:

MISSION PHARMACAL COMPANY

San Antonio, TX 78230 1355

R2022

SPL Unclassified Section 100 Capsule Bottle Label

NDC 0178-0740-01

Uribel ™

EACH CAPSULE CONTAINS

Methenamine 118 mg

Sodium Phosphate Monobasic 40.8 mg

Phenyl Salicylate 36 mg

Methylene Blue 10 mg

Hyoscyamine Sulfate 0.12 mg

Rx ONLY

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Urinary alkalizers and thiazide diuretics: May cause the urine to become alkaline reducing the effectiveness of methenamine by inhibiting its conversion to formaldehyde.

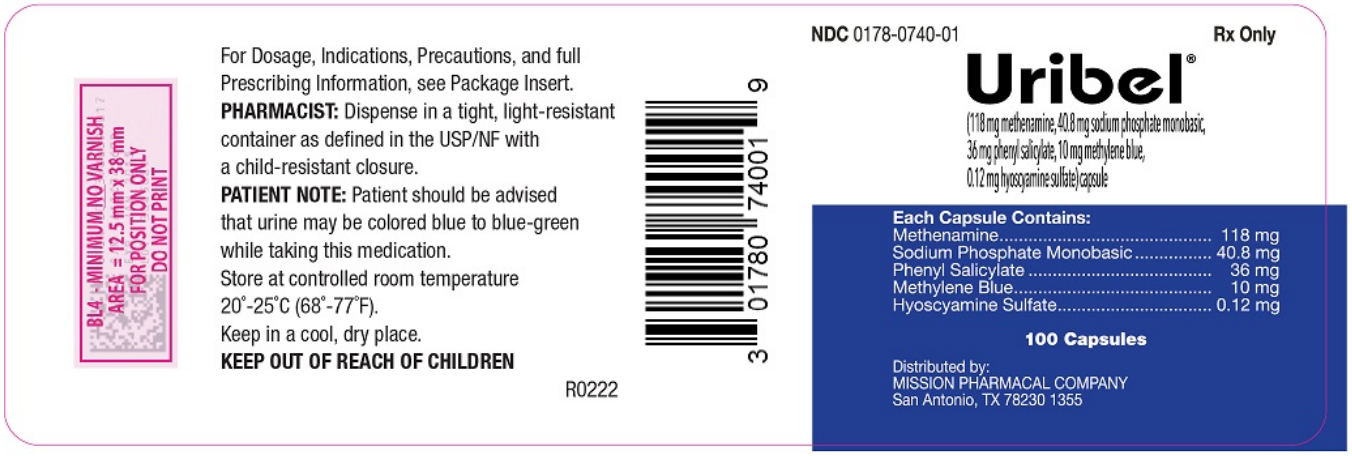
Antimuscarinics: Concurrent use may intensify antimuscarinic effects of hyoscyamine because of secondary antimuscarinic activities of these medications.

Antacids/antidiarrheals: Concurrent use may reduce absorption of hyoscyamine resulting in decreased therapeutic effectiveness. Concurrent use with antacids may cause urine to become alkaline reducing the 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, therefore, caution is recommended.
Ketoconazole and hyoscyamine may cause increased gastrointestinal pH. Concurrent administration with hyoscyamine may result in marked reduction in the absorption of ketoconazole. Patients should be advised to take this combination at least 2 hours after ketoconazole.

Monoamine oxidase (MAO) inhibitors: Concurrent use with hyoscyamine 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 and/or stools may become blue to blue-green as a result of the excretion of methylene blue.



URIBEL

methenamine, sodium phosphate, monobasic, monohydrate, phenyl salicylate, methylene blue, and hyoscyamine sulfate capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0178-0740
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHENAMINE (UNII: J50OIX95QV) (METHENAMINE - UNII:J50OIX95QV)	METHENAMINE	118 mg
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE	40.8 mg
PHENYL SALICYLATE (UNII: 28A37T47QO) (PHENYL SALICYLATE - UNII:28A37T47QO)	PHENYL SALICYLATE	36 mg
METHYLENE BLUE (UNII: T42P99266K) (METHYLENE BLUE CATION - UNII:ZMZ79891ZH)	METHYLENE BLUE	10 mg
HYOSCYAMINE SULFATE (UNII: F2R8V82B84) (HYOSCYAMINE - UNII:PX44XO846X)	HYOSCYAMINE SULFATE	0.12 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	purple	**Score**	no score
Shape	CAPSULE (Oblong shape)	**Size**	19mm
Flavor		**Imprint Code**	S;111
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0740-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	04/15/2019	12/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/15/2019	12/31/2024

Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (927126893)

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