UROAV-B- methenamine, sodium phosphate, monobasic, anhydrous, phenyl salicylate, methylene blue and hyoscyamine sulfate capsule
Apace Packaging, LLC

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.

UroAv-B Urinary Antiseptic (Product contract packaged by Apace Packaging, LLC)

Rx Only

DESCRIPTION

UroAv-B Capsules for oral administration.

Each tablet contains:

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

Inactive ingredients: Lactose, Polyethylene Glycol, Crospovidone, Magnesium Stearate, Colloidal Silicon Dioxide, FD&C Blue # 1, FD&C Red # 3, Titanium Dioxide, Gelatin.

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.

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.

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.

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.

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.

CLINICAL PHARMACOLOGY

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 amount 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 a pH greater than 6.8.

SODIUM PHOSPHATE MONOBASIC an acidifier, helps to maintain an acid pH in the urine necessary for the degradation of methenamine.

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.

HYOSCYAMINE SULFATE is a parasympatholytic drug 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. Protein binding for hyoscyamine sulfate is moderate and biotransformation is hepatic.

INDICATIONS AND USAGE

UroAv-B Capsules are 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

UroAv-B Capsules are contraindicated in patients with a hypersensitivity to any of the ingredients. Risk-benefit should be 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.

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.

PRECAUTIONS

Cross sensitivity and/or related problems:
Patients intolerant of other belladonna alkaloids or other 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 have not been done in either animals or humans. It is not known whether UroAv-B Capsules can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. UroAv-B Capsules should be given to a pregnant woman only if clearly needed.

Nursing mothers:

Methenamine and traces of hyoscyamine are excreted in breast milk. Caution should be exercised when UroAv-B Capsules are administered to a nursing mother.

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 the usual doses of the belladonna alkaloids with excitement, agitation, drowsiness, or confusion.

ADVERSE REACTIONS

Cardiovascular - rapid pulse, flushing

Central Nervous System - blurred vision, dizziness, drowsiness

Respiratory - shortness of breath or troubled breathing

Genitourinary - difficult micturition, acute urinary retention

Gastrointestinal -dry mouth, nausea and vomiting

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 AvKARE, Inc. at 1-855-361-3993 or FDA at 1-800-FDA-1088 or 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.

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.

Drug Abuse And Dependence

A dependence on the use of UroAv-B Capsules has not been reported and due to the nature of its ingredients, abuse of UroAv-B 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 the poison control center at 1-800-222-1222, or your local emergency room immediately.

DOSAGE AND ADMINISTRATION

Adults: One tablet orally 4 times per day followed by liberal fluid intake.

Pediatric: Dosage must be individualized by physician for older children. Not recommended for use in children six years of age or younger.

HOW SUPPLIED

UroAv-B Capsules are blue capsules imprinted with 200, available in bottles of 100 capsules, (NDC: 42291-852-01).

STORAGE

Store in a cool, dry place at controlled room temperature 15° to 30°C (59° to 86°F). Keep container tightly closed. Protect from moisture and direct sunlight.

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

WARNING:

Keep this and all drugs out of reach of children.

Rx Only

Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. 10/14
AV 03/16 (P)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

AvKARE

NDC 42291-852-01

UroAv-B Urinary Antiseptic

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

100 Capsules Rx Only

Dosage and Administration:
Adults: One capsule orally 4 times per day followed by liberal fluid intake.

Pediatric: Dosage must be individualized by physician for older children. Not recommended for use in children six years of age or younger.

Note: Patient should be advised that urine may be colored blue to blue-green while taking this medication.

SEE PRODUCT LITERATURE FOR FULL PRESCRIBING INFORMATION.

Tamper evident seal under cap. Do not use if foil seal is missing or broken.

Storage: Store in a cool, dry place at controlled room temperature 15° to 30°C (59° to 86°F). Keep container tightly closed. Protect from moisture and direct sunlight.

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

To report SUSPECTED ADVERSE REACTIONS, contact AvKARE, Inc. at 1-855-361-3993.

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Manufactured for:
AvKARE, Inc.
Pulaski, TN 38478

Mfg. Rev. 10/2014 AV 03/16 (P)

UROAV-B

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

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:15338-503(NDC:58657-456)
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, ANHYDROUS (UNII: KH7I04HPUU) (SODIUM CATION - UNII:LYR4M0NH37)	SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS	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**
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	

Product Characteristics			
Color	blue	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	200
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:15338-503-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/25/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/25/2016	

Labeler - Apace Packaging, LLC (361961142)

Establishment

Name	Address	ID/FEI	Business Operations
Apertus Pharmaceuticals, LLC		078834955	manufacture(15338-503)

Establishment

Name	Address	ID/FEI	Business Operations
Apace Packaging, LLC		361961142	repack(15338-503) , label(15338-503)

Revised: 5/2018 Apace Packaging, LLC