Urinary Antiseptic/Antispasmodic

- Eases Discomfort
- Water Soluble
- Renders Urine Blue

Aspirin free • No restriction for duration of therapy
Well tolerated • Easy dosing 4X per day

EACH TABLET CONTAINS:

- Methenamine, USP 81.6 mg
- Monobasic Sodium Phosphate, USP 40.8 mg
- Methylene Blue, USP 10.8 mg
- Hyoscyamine Sulfate, USP 0.12 mg

INDICATIONS:
For the treatment of symptoms of irritative voiding, hypermotility, urinary tract infections and discomfort from urinary diagnostic procedures.

DOSAGE & ADMINISTRATION:

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

CHILDREN (over 6 years of age)
Dosage must be individualized by physician. (Not recommended for use in children under 6 years of age.)

See package insert for full prescribing information.
Necessary for the degradation of methenamine. Gastrointestinal tract and is rapidly reduced to leukomethylene blue which is clinically significant as it does not hydrolyze at pH greater than 6.8. Tissues. Methenamine is freely distributed to body tissue and fluids but is not binding: some formaldehyde is bound to substances in the urine and surrounding tissues. Of this amount at pH 5, approximately 20% is formaldehyde. Protein binding is moderate. Methylene blue exists as dark green crystals. It is soluble in water and in chloroform; sparingly soluble in alcohol. Monobasic Sodium Phosphate exists as a white crystalline powder. Its solutions are acidic to litmus. It is freely soluble in water and practically insoluble in alcohol.

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% to 90% reaches the urine unchanged at which point it is excreted. Its protein binding is moderate. Methenamine exists as colorless, lustrous crystals or white crystalline powder. Its solutions are alkaline to litmus. It is freely soluble in water and practically insoluble in alcohol.

Indications and Usage
UROGESIC-BLUE™ is indicated for the treatment of symptoms of irritative voiding. Indicated for the relief of local symptoms, such as hypermotility which accompany lower urinary tract infections and as antispasmodic. Indicated for the relief of urinary tract symptoms caused by diagnostic procedures.

Contraindications
UROGESIC-BLUE™ is 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, mitral stenosis); gastrointestinal tract obstructive disease: glaucoma: myasthenia gravis: acute urinary retention may be associated with use in patients with these conditions. Use with caution in patients with hepatic, renal, or cardiovascular disease; irritable bowel syndrome; 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 may be intolerant of this medication also.

Pregnancy/Reproduction (Pregnancy Category C) - hyoscyamine and methenamine cross the placenta. Studies have not been done in animals or humans. It is not known whether UROGESIC-BLUE™ tablets cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. UROGESIC-BLUE™ tablets 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.

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 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 antimuscarinics effects of hyoscyamine because of secondary antimuscarinic activities of these medications); antacids (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; antihypertensives (concurrent use with methenamine 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 feaces 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 troubled breathing
Genitourinary - difficulty micturition, acute urinary retention
Gastrointestinal - dry mouth, nausea/vomiting

Drug Abuse and Dependence
A dependence on the use of UROGESIC-BLUE™ has not been reported and due to the nature of its ingredients, abuse of UROGESIC-BLUE™ is not expected.

Overdosage
Emesis or gastric lavage. Slow intravenous administration of physostigmine in doses of 1 mg to 4 mg (0.5 mg 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 up to 6 years of age.

How Supplied
UROGESIC-BLUE™ are light blue to blue, oval, biconvex tablets debossed with “ED UB” with scoreline on one side and plain on the other side. Supplied in bottles of 100 tablets (NDC 0485-0151-01).

Storage
Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Protect from moisture and direct sunlight.

Caution | RX Only

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Urogescis BLUE™

Manufactured for:
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111 W. Mulberry St. - Ripley, Mississippi 38663
www.wcpharma.com

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