Hyoscyamine Sulfate is an alkaloid of belladonna. Exists as a white crystalline solid with a melting point of 192°-194° C. It is very soluble in water but is not clinically significant as it does not hydrolyze at pH greater than 6.8. It is a sphincter and smooth muscle relaxant. It is readily absorbed from the stomach and gastrointestinal tract and rapidly reduced to leukomethylene blue which is excreted in the urine. The color blue-green is harmless and will subside after medication is stopped. Call your doctor or physician for medical advice about side effects.

**DESCRIPTION**: Uribel™ capsules contain the following inactive ingredients: Dicalcium Phosphate, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Red No. 40, FD&C Yellow No. 6, gelatin, glycerin, hydrogenated soybean oil, magnesium stearate, polyethylene glycol 400, and titanium dioxide.

**INDICATIONS AND USAGE**: Uribel™ is indicated for the treatment of symptoms of irritative voiding. It is not indicated for the treatment of symptoms of obstructive voiding.

**CONTRAINDICATIONS**:

1. Cross sensitivity and/or related problems - Patients with a history of allergy to any of the constituents of Uribel™ should not receive this medication.
2. Pregnancy - Uribel™ should be given to a pregnant woman only if clearly needed. Prolonged use - Risk benefits should be carefully considered when the following medical conditions are present: glaucoma; acute urinary retention; bowel obstruction; prostatic hypertrophy; mitral stenosis; cardiovascular disease; mitral regurgitation; and irritable colon. Pediatric Use - Safety and effectiveness in pediatric patients have not been established.

**WARNINGS**:

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**ADVERSE REACTIONS**: The most commonly reported adverse reactions, all of which are mild, are:

- Central nervous system: blurred vision, dizziness, drowsiness, excitement, headache, tingling, weakness, numbness
- Gastrointestinal: dry mouth, nausea and vomiting
- Cardiovascular: rapid heartbeat, flushing
- Respiratory: choking, shortness of breath
- Skin: rash, urticaria
- Blood: anemia
- Other: sweating, excessive thirst, weight gain

**DRUG ABUSE AND DEPENDENCE**: A dependence on the use of Uribel™ capsules has not been reported. The abuse potential of Uribel™ capsules is not expected.

**OVERDOSAGE**: Symptoms of hyoscyamine toxicity have not been reported after the ingestion of large doses of Uribel™ capsules. In the event of an overdose, normal supportive measures should be taken. In addition, Gastrointestinal decontamination with activated charcoal should be considered.