TROSPILAN®

**TROSPILAN® Tablets**

**INDICATIONS AND USAGE**

Trospium Chloride Tablets are a quaternary ammonium compound with an anticholinergic action. Its mechanism of action involves blocking the effects of acetylcholine on smooth muscle, the parasympathetic nervous system, and the central nervous system. It is effective in the management of overactive bladder (OAB) due to the symptoms of urgency, frequency, and urge urinary incontinence in adults.

**CONTRAINdications**

- Hypersensitivity to Trospium Chloride or other quaternary ammonium compounds.
- Patients with a known hypersensitivity to any excipient contained in the formulation.
- Patients with known hypersensitivity to dicyclomine or atropine, as Trospium Chloride is closely related chemically to these agents.

**WARNINGS AND PRECAUTIONS**

- Trospium Chloride Tablets should be used with caution in patients with GI obstructions due to the risk of urinary retention.
- Patients with known allergy to quaternary ammonium compounds or related agents should be monitored closely.
- Patients should use Trospium Chloride Tablets with caution in the presence of intraocular pressure.
- Patients with a known history of urinary retention or bladder neck obstruction should be treated with caution.

**DRUG INTERACTIONS**

Patients taking Trospium Chloride Tablets should be advised to consult their healthcare provider before taking any new medications or supplements to avoid potential drug interactions.

**ADVERSE REACTIONS**

The most common adverse reactions reported with Trospium Chloride Tablets are dry mouth, constipation, flatulence, and flatus. Other reported adverse reactions include dizziness, dryness of the skin, and nausea.

**DOSE AND ADMINISTRATION**

The recommended dose is 20 mg twice daily before meals or at least one hour before meals. The dose may be increased to 40 mg twice daily if tolerated by the patient.

**OVERDOSAGE**

Overdose with Trospium Chloride Tablets may result in severe anticholinergic effects, such as dry mouth, constipation, and blurred vision. In case of an overdose, supportive measures should be taken, including gastric lavage and supportive care.

**HOW SUPPLIED**

Trospium Chloride Tablets are supplied in bottles of 30 mg, 50 mg, and 100 mg tablets. Each 30 mg tablet contains 30 mg of trospium chloride as the hydrochloride salt.

**FULL PRESCRIBING INFORMATION**

This information is available from the FDA at www.fda.gov. Please consult the full prescribing information for complete details on the use, dosage, precautions, and adverse reactions of Trospium Chloride Tablets.
Drugs and Other Medications

Placbo-controlled studies employing urodynamics were conducted in patients with conditions characterized by involuntary detrusor contractions. The results demonstrate that Tangier's product characteristics of Trospium Chloride Tablets include maximum cystometric bladder capacity and volume at first detrusor contraction.

Electrolytes

The effect of 20 mg twice daily and up to 100 mg twice daily Trospium Chloride Tablets on QT interval was evaluated in a single-dose study in 72 healthy subjects given placebo, 10 mg, 20 mg, 50 mg, or 100 mg doses of Trospium Chloride Tablets. The effect of Trospium Chloride Tablets on QT interval was assessed at the trough and at the peak of its plasma concentration. The highest concentrations of Trospium Chloride Tablets were observed 1 to 2 hours after administration.

Polyethylene glycol 3350.

The safety of Trospium Chloride Tablets was evaluated in 2 placebo-controlled trials in patients with overactive bladder, with or without urgency incontinence. One study included 208 patients who were treated with Trospium Chloride Tablets 20 mg twice daily for 6 months. The other study included 214 patients who were treated with Trospium Chloride Tablets 20 mg twice daily for 12 months.

Meds and Foam

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