Toltrex®

Tolterodine Tartrate INN Tablet

Presentation
Toltrex® 2: Each tablet contains Tolterodine Tartrate INN 2 mg.

Description
Tolterodine is a competitive, specific muscarinic receptor antagonist, which exhibits selectivity for the urinary bladder over salivary glands. One of the tolterodine metabolites (5-hydroxymethyl derivative) exhibits a pharmacological profile similar to that of the parent compound. In extensive metabolisers this metabolite contributes significantly to the therapeutic effect.

Indications
Toltrex is indicated for the treatment of overactive bladder with symptoms of urinary urgency, frequency, and/or urge incontinence.

Dosage and administration
The recommended dose is 2 mg b.i.d. In the case of troublesome side-effects the dose may be reduced from 2 mg to 1 mg b.i.d.
The recommended dose is 1 mg b.i.d. for patients with impaired renal function, impaired liver function, or receiving concomitant ketoconazole or other potent CYP3A4 inhibitors.

Side effects
Tolterodine may cause mild-to-moderate antimuscarinic effects, like dryness of the mouth, dyspepsia and reduced lacrimation.

Contraindications
Tolterodine is contraindicated in patients with known hypersensitivity to tolterodine or any other component of the drug, urinary retention and uncontrolled narrow angle glaucoma.

Precautions
Tolterodine should be used with caution in the patients at risk for urinary retention & decreased gastrointestinal motility, with impaired renal & hepatic function and with myasthenia gravis.

Use in pregnancy & lactation
There are no studies in pregnant women. Therefore, tolterodine should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus. Use of tolterodine during lactation should be avoided since no data on excretion into breast milk in humans are available.

Drug Interaction
Ketoconazole, a potent inhibitor of CYP3A4, significantly increased plasma concentrations of tolterodine when co-administered to poor metabolisers. For patients receiving ketoconazole or other potent CYP3A4 inhibitors, the recommended total daily dose is 2 mg.

Overdosage
Treatment of overdosage with tolterodine should consist of activated charcoal. Activated charcoal is usually most effective when administered within 1-hour of ingestion. Ipecac-induced emesis is not recommended, and dialysis is not likely to be of benefit as tolterodine is highly protein-bound.

Storage
Do not store above 30 ^{0}C. Keep away from light and out of the reach of children.

Commercial Pack
Toltrex® 2: Each box contains 3 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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