Ucol® 2

Tolterodine Tartrate 2 mg

COMPOSITION
Ucol" 2 tablet: Each film coated tablet contains Tolterodine Tartrate INN 2 mg.

PHARMACOLOGY
Tolterodine is a competitive, specific muscarinic receptor antagonist which exhibits selectivity for the urinary bladder over salivary glands, which have been demonstrated in non-clinical pharmacological in vivo studies.Tolterodine has a high specificity for muscarinic receptors. A major active metabolite (5-hydroxymethyl derivative) of tolterodine exhibits a pharmacological profile which is similar to that of the parent compound. In extensive metabolisers this metabolite contributes significantly to the therapeutic effect of tolterodine.The effect of treatment can be expected within 4 weeks.

INDICATIONS AND USAGE
Ucol" 2 tablet: (Tablet 2 mg) are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

DOSAGE AND ADMINISTRATION
Ucol"2 tablet: The recommended dose for Ucol" is 2 mg b.i.d. In case of troublesome side effects the dose may be reduced from 2 mg to 1 mg b.i.d. The recommended total daily dose of tolterodine is 2 mg (1 mg b.i.d.) for patients with impaired renal function, impaired liver function, or receiving concomitant medication with potent CYP3A inhibitors, such as macrolide antibiotics (e.g. erythromycin and clarithromycin) or azole antifungal agents (e.g. ketoconazole, itraconazole and miconazole). After six months the need for further treatment should be considered.

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

PRECAUTION
Tolterodine should be used with caution in the following patients:
•At risk for urinary retention
•at risk for decreased gastrointestinal motility
•With impaired renal function
•With impaired hepatic function
•With uncontrolled narrow-angle glaucoma
Organic reasons for urge and frequency should be considered before treatment

ADVERSE EFFECTS
Tolterodine may cause mild to moderate antimuscarinic effects, like dryness of mouth, dyspepsia and/or reduced lacrimation.

DRUG INTERACTION
Pharmacokinetic interactions are possible with other drugs metabolised by or inhibiting cytochrome P450 2D6 (CYP2D6) or CYP3A4. Concomitant treatment with fluoxetine does not result in a clinically significant interaction. Ketoconazole, a potent inhibitor or other CYP3A, significantly increased plasma concentrations of tolterodine when co-administered to poor metabolisers (i.e. persons devoid of CYP2D6 metabolic pathway).
Clinical studies have shown no interactions with warfarin or combined oral contraceptives (ethinyloestradiol/levonorgestrel).

PREGNANCY AND LACTATION
Pregnancy Category C .There are no studies in pregnant women. Therefore, tolterodine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Use of tolterodine during lactation should be avoided since no data on excretion of the drug into breast milk in humans is available.

PEDIATRIC USE
EGcacy in the pediatric population has not been demonstrated.

STORAGE CONDITION
Store in a cool and dry place(below 30°c.). Protect from light. Keep out of the reach of children.

HOW SUPPLIED
Ucol" 2 tablet: Box containing 60 tablets in Alu-PVC blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH