Oriham™

Atomoxetine Capsule

Presentation
Oriham™ 10: Each capsule contains Atomoxetine Hydrochloride USP equivalent to Atomoxetine 10 mg.

Description
Atomoxetine is a selective norepinephrine reuptake inhibitor. The precise mechanism of action of Atomoxetine is unknown, but is thought to be related to selective inhibition of the pre-synaptic norepinephrine transporter.

Indications and usage
Atomoxetine is indicated for treatment of Attention-Deficit/Hyperactivity Disorder (ADHD).

Dosage and administration

Body weight	Initial dose	Recommended dose	Maximum dose
Children and adolescents up to 70 kg	0.5 mg/kg	1.2 mg/kg	1.4 mg/kg
Children and adolescents over 70 kg and adults	40 mg	80 mg	100 mg

For patients with moderate hepatic insufficiency (Child-Pugh Class B), initial and target doses should be reduced to 50% of the normal dose. For patients with severe hepatic insufficiency (Child-Pugh Class C), initial dose and target doses should be reduced to 25% of normal.

Adverse reactions
The most common adverse reactions of Atomoxetine are nausea, vomiting, fatigue, decreased appetite, abdominal pain, and somnolence, constipation, dry mouth, dizziness, erectile dysfunction, and urinary hesitation and retention.

Contraindications
Atomoxetine is contraindicated in patients with a known hypersensitivity to Atomoxetine, use of Atomoxetine within 2 weeks after discontinuing MAOI or other drugs that affect brain monoamine concentrations, Narrow Angle Glaucoma, Pheochromocytoma and Severe Cardiovascular.

Precautions
Caution should be exercised when Atomoxetine is prescribed in patients with known Cardiovascular diseases, suicidal ideation, severe liver injury, hypertension, tachycardia, psychotic or manic symptoms, bipolar disorder, aggressive behavior or hostility, possible allergic reactions, including anaphylactic reactions, angioneurotic edema, urticaria, and rash.

Drug interactions
Atomoxetine should be used with caution in combination with:
• Monoamine Oxidase Inhibitors
• Antihypertensive drugs-possible effects on blood pressure
• CYP2D6 Inhibitors-concomitant use may increase Atomoxetine steady-state plasma concentrations

Use in specific population
Pregnancy & Lactation: There are no adequate and well-controlled studies in pregnant women. Lactation studies have not been conducted to assess the presence of Atomoxetine in human milk, the effects of Atomoxetine on the breastfed infant, or the effects of Atomoxetine on milk production.
Pediatric use: The safety, efficacy, and pharmacokinetics of Atomoxetine in pediatric patients less than 6 years of age have not been evaluated.
Geriatric use: The safety, efficacy and pharmacokinetics of Atomoxetine in geriatric patients have not been evaluated.
Hepatic Impairment: Atomoxetine exposure is increased in moderate (Child-Pugh Class B) (2-fold increase) and severe (Child-Pugh Class C) (4-fold increase) hepatic insufficiency. Dosage adjustment is recommended for patients with moderate or severe hepatic insufficiency.
Renal Impairment: No dose adjustment is recommended for patients with renal impairment of any severity.

Overdose
There have been no reports of death involving overdose of Atomoxetine alone, including intentional overdoses at amounts up to 1400 mg. The most commonly reported symptoms accompanying overdoses of Atomoxetine were seizures, gastrointestinal symptoms, somnolence, dizziness, tremor, abnormal behavior, hyperactivity, tachycardia, blood pressure increased, mydriasis and dry mouth. Most events were mild to moderate.

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

Commercial Pack
Oriham™ 10: Each box contains 3 blister strips of 10 capsules.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
™ Trademark

V.N.01
ORH