Abridged Prescribing Information:

Active Ingredient: Axepta 10 / 18 / 25 / 40 / 60 capsule contain Atomoxetine HCl Tablets 10 mg, 18 mg, 25 mg, 40 mg, 60mg Indication**:** for the treatment of attention deficit hyperactivity disorders **Dosage & Administration**: ADHD: Children and adolescents up to 70 kg Initial daily dose: 0.5 mg/kg, increase after minimum 3 days to target total daily dose: 1.2 mg/kg; maximum total daily dose: 1.4 mg/kg or 100 mg whichever is less. Children and adolescents >70 kg and adults-Initial daily dose: 40 mg, increase after minimum 3 days to target total daily dose: 80 mg; maximum total daily dose: 100 mg. **Administration:** Once a day (in the morning) or twice daily (morning and late afternoon/early evening) **Contraindications:** Hypersensitivity to atomoxetine or other constituents of product, use within 2 weeks after discontinuing MAOI or other drugs that affect brain monoamine concentrations. Narrow Angle Glaucoma. Pheochromocytoma or history of pheochromocytoma **Warnings & Precautions**: Monitor for suicidality, clinical worsening, and unusual changes in behaviour. Should be discontinued and not restarted in patients with jaundice or laboratory evidence of liver injury, Serious Cardiovascular Events- Sudden death, stroke and myocardial infarction have been reported in association with atomoxetine treatment, Emergent Cardiovascular Symptoms-- Patients should undergo prompt cardiac evaluation, Effects on Blood Pressure and Heart Rate – Can increase blood pressure and heart rate; orthostasis, syncope and Raynaud's phenomenon may occur. Use with caution in patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease, Emergent Psychotic or Manic Symptoms- Consider discontinuing treatment if such new symptoms occur, Bipolar Disorder – Screen patients to avoid possible induction of a mixed/manic episode, Aggressive behavior or hostility should be monitored. Possible allergic reactions, including anaphylactic reactions, angioneurotic edema, urticaria, and rash. Urinary hesitancy and retention may occur. Priapism – Prompt medical attention is required in the event of suspected priapism, height and weight should be monitored in pediatric patients. **Pregnancy & Lactation**: Pregnancy/Lactation - Pregnant or nursing women should not use unless potential benefit justifies potential risk to fetus or infant. **Interactions:** Monoamine Oxidase Inhibitors, CYP2D6 Inhibitors - Concomitant use may increase atomoxetine steady state plasma concentrations in Ems, Pressor Agents - Possible effects on blood pressure, Albuterol (or other beta2 agonists) - Action of albuterol on cardiovascular system can be potentiated. **Adverse Reactions:** Most common adverse reactions -Child and Adolescent Clinical Trials – Nausea, vomiting, fatigue, decreased appetite, abdominal pain, and somnolence. Adult Clinical Trials – Constipation, dry mouth, nausea, fatigue, decreased appetite, insomnia, erectile dysfunction, urinary hesitation and/or urinary retention and/or dysuria, dysmenorrhea, and hot flush. **Overdose:** The most commonly reported symptoms accompanying acute and chronic overdoses of Atomoxetine were gastrointestinal symptoms, somnolence, dizziness, tremor, and abnormal behavior. Hyperactivity and agitation have also been reported. Signs and symptoms consistent with mild to moderate sympathetic nervous system activation (e.g., tachycardia, blood pressure increased, mydriasis, dry mouth) have also been observed. Most events were mild to moderate. Less commonly, there have been reports of QT prolongation and mental changes, including disorientation and hallucinations. Because atomoxetine is highly protein bound, dialysis is not likely to be useful in the treatment of overdose. *(For details, please refer full prescribing information)*

Version date: 10/03/21. If you require any further information, please reply us on productqueries@intaspharma.com