

Abridged Prescribing Information:

Active Ingredient: SERTIMA 25 / 50 / 100 tablets contains Sertraline HCl 25 mg, 50 mg, 100 mg **Indication:** Treatment of (1) major depressive disorder (MDD) in adults (2) obsessive-compulsive disorder (OCD), (3) panic disorder (PD) in adults, with or without agoraphobia, (4) posttraumatic stress disorder (PTSD) in adults, (5) premenstrual dysphoric disorder (PMDD) in adults, (6) social anxiety disorder (SAD, or social phobia) in adults. **Dosage and administration:** Adults MDD & OCD: 50 mg once a day, PD, PTSD, SAD: initially 25 mg once a day X 1 week, thereafter 50 mg once a day PMDD: initially 50 mg once a day [either daily throughout the menstrual cycle (MC) or limited to the luteal phase of the MC], for non-responders increase dose at the onset of each new MC by 50 mg increments /menstrual cycle up to 150 mg/d (when dosing daily throughout the MC), or 100 mg/d (when dosing during the luteal phase of the MC) Children and adolescents OCD: Ages 6-12: 25 mg once a day, Ages 13-17: 50 mg once a day Maintenance/Continuation/Extended Treatment MDD: 50-200 mg/d, PTSD: 50-200 mg/d, SAD: 50-200 mg/d, OCD & PD: 50-200 mg/d. **Contraindications:** Concomitant use of monoamine oxidase inhibitors (MAOIs), or use within 14 days of stopping MAOIs, Concomitant use of pimozide, Known hypersensitivity to sertraline or excipients. **Warnings & Precautions:** Serotonin Syndrome: Increased risk when co-administered with other serotonergic agents (e.g., SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue SERTIMA and initiate supportive treatment. Increased Risk of Bleeding: Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), other antiplatelet drugs, warfarin, and other anticoagulants may increase this risk. Activation of Mania/Hypomania: Screen patients for bipolar disorder. Seizures: Use with caution in patients with seizure disorders. Angle Closure Glaucoma: Avoid use of antidepressants, including SERTIMA, in patients with untreated anatomically narrow angles. **Pregnancy & Lactation:** Pregnancy: Third trimester use may increase risk for persistent pulmonary hypertension and withdrawal in the neonate. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for SERTIMA and any potential adverse effects on the breastfed infant from the drug or from the underlying maternal condition **Drug Interaction:** Protein-bound drugs: Monitor for adverse reactions and reduce dosage of SERTIMA or other protein-bound drugs (e.g., warfarin) as warranted. CYP2D6 substrates: Reduce dosage of drugs metabolized by CYP2D6. **Adverse Reactions:** The Most common adverse reactions (>5% and twice placebo) in pooled placebo-controlled MDD, OCD, PD, PTSD, SAD and PMDD clinical trials were nausea, diarrhea/loose stool, tremor, dyspepsia, decreased appetite, hyperhidrosis, ejaculation failure, and decreased libido **Overdose:** The most common signs and symptoms associated with non-fatal SERTIMA overdose were somnolence, vomiting, tachycardia, nausea, dizziness, agitation and tremor. No cases of fatal overdose with only sertraline have been reported. Other important adverse events reported with SERTIMA overdose (single or multiple drugs) include bradycardia, bundle branch block, coma, convulsions, delirium, hallucinations, hypertension, hypotension, manic reaction, pancreatitis, QT-interval prolongation, Torsade de Pointes, serotonin syndrome, stupor, and syncope. **Overdose Management** No specific antidotes for SERTIMA are known. *(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