SERENATA

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Abbreviated Prescribing information for SERENATA (Sertraline Hydrochloride 50mg and 100mg Tablet.) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Sertraline hydrochloride is a selective serotonin reuptake inhibitor (SSRI) for oral administration.

INDICATIONS: For the treatment of depression

DOSAGE AND ADMINISTRATION: An initial dosage of 50mg once daily increased if necessary, in increment of 50mg at interval of at least a week to a maximum of 200mg daily.

CONTRAINDICATION: The use of Monoamine Oxidase Inhibitors (MAOIs) with Sertraline hydrochloride is contraindicated because of an increased risk of serotonin syndrome. Concomitant use in patients taking pimozide is contraindicated. Sertraline is contraindicated in patients with a hypersensitivity to sertraline or any of the inactive ingredients of tablet.

WARNINGS & PRECAUTIONS: Clinical Worsening and Suicide Risk- Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior. It is generally believed that treating depressive episode with an antidepressant alone may increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. The development of a potentially life-threatening serotonin syndrome has been reported. Angle-Closure Glaucoma: The pupillary dilation occurs following the use of sertraline which may trigger angle closure attack in a patient. During premarketing testing, hypomania or mania occurred. Significant weight loss may be an undesirable result of treatment with sertraline. Sertraline should be introduced with care in patients with a seizure disorder. During marketing of Sertraline there have been spontaneous reports of adverse events occurring upon discontinuation including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g. paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. Sertraline hydrochloride is associated with a mean decrease in serum uric acid. Hyponatremia may occur as a result of treatment with Sertraline. There have been rare reports of altered platelet function in patients taking Sertraline. Patients should be cautioned about the concomitant use of Sertraline and NSAIDs, aspirin, warfarin, or other drugs that affect coagulation because of increased risk of bleeding. The concomitant use of Sertraline and alcohol is not advised. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy or they are breast feeding an infant. False-positive urine immunoassay screening tests for benzodiazepines have been reported.

DRUG INTERACTIONS: Co administration of Drugs Highly Bound to Plasma Proteins, drugs that prolong the QT interval, CNS Active Drugs, drugs Metabolized by P450 2D6, triptans and hypoglycemic drugs. Caution is indicated in the co-administration of TCAs with sertraline, because sertraline may inhibit TCA metabolism.

ADVERSE REACTIONS: Acute renal failure, anaphylactoid reaction, angioedema, blindness, optic neuritis, cataract, increased coagulation times, bradycardia, AV block, atrial arrhythmias, QT-interval prolongation, ventricular tachycardia (including Torsade de Pointes arrhythmias), cerebrovascular spasm (including reversible cerebral vasconstriction syndrome and Call-Fleming syndrome), hypothyroidism, agranulocytosis, aplastic anemia, pancytopenia, leukopenia, thrombocytopenia, lupus-like syndrome, serum sickness, diabetes mellitus, hyperglycemia, galactorrhea, hyperprolactinemia, extrapyramidal symptoms, oculogyric crisis, serotonin syndrome, psychosis, pulmonary hypertension, Stevens-Johnson syndrome, vasculitis, photosensitivity and other severe cutaneous disorders, rare reports of pancreatitis, elevated enzymes, increased bilirubin, hepatomegaly, hepatitis, jaundice, abdominal pain, vomiting, liver failure and death.

MARKETED BY:

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(Additional information is available on request)