SERTA

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

Abbreviated Prescribing information for SERTA (Sertraline Tablets I.P.) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Sertraline is a potent and specific inhibitor of neuronal serotonin (5 HT) uptake in vitro, which results in the potentiation of the effects of 5-HT in animals. It has only very weak effects on norepinephrine and dopamine neuronal reuptake. At clinical doses, sertraline blocks the uptake of serotonin into human platelets. It is devoid of stimulant, sedative or anticholinergic activity or cardiotoxicity in animals. In controlled studies in normal volunteers, sertraline did not cause sedation and did not interfere with psychomotor performance. In accord with its selective inhibition of 5-HT uptake, sertraline does not enhance catecholaminergic activity. Sertraline has no affinity for muscarinic (cholinergic), serotonergic, dopaminergic, adrenergic, histaminergic, GABA or benzodiazepine receptors. The chronic administration of sertraline in animals was associated with down-regulation of brain norepinephrine receptors as observed with other clinically effective antidepressants and antiobsessional drugs. Sertraline has not demonstrated potential for abuse**.**

INDICATION: For the treatment of Major depressive disorder, obsessive compulsive disorder, panic disorders.

DOSAGE AND ADMINISTRATION: Film Coated Tablet. Sertraline should be administered once daily, either in the morning or evening. Sertraline tablet can be administered with or without food.

CONTRAINDICATION: Hypersensitivity to the active substance or any of the excipients.

Concomitant treatment with irreversible monoamine oxidase inhibitors (MAOIs) is contraindicated due to the risk of serotonin syndrome with symptoms such as agitation, tremor and hyperthermia. Sertraline must not be initiated for at least 14 days after discontinuation of treatment with an irreversible MAOI.

Sertraline must be discontinued for at least 7 days before starting treatment with an irreversible MAOI. Concomitant intake of pimozide is contraindicated**.**

WARNINGS & PRECAUTIONS: 1) Serotonin Syndrome (SS) or Neuroleptic Malignant Syndrome (NMS): The development of potentially life-threatening syndromes like serotonin syndrome (SS) or Neuroleptic Malignant Syndrome (NMS) has been reported with SSRIs, including treatment with sertraline.2) Switching from Selective Serotonin Reuptake Inhibitors (SSRIs), antidepressants or antiobsessional drugs: There is limited controlled experience regarding the optimal timing of switching from SSRIs, antidepressants or anti-obsessional drugs to sertraline. 3) Other serotonergic drugs e.g. tryptophan, fenfluramine and 5-HT agonists: Co-administration of sertraline with other drugs which enhance the effects of serotonergic neurotransmission such as amphetamines, tryptophan or fenfluramine or 5-HT agonists, or the herbal medicine, St John's Wort (*hypericum perforatum*), should be undertaken with caution and avoided whenever possible due to the potential for a pharmacodynamic interaction. 4) QTc Prolongation/Torsade de Pointes (TdP): Cases of QTc prolongation and Torsade de Pointes (TdP) have been reported during post-marketing use of sertraline. 5)Activation of hypomania or mania:Manic/hypomanic symptoms have been reported to emerge in a small proportion of patients treated with marketed antidepressant and anti-obsessional drugs, including sertraline. 6) Schizophrenia: Psychotic symptoms might become aggravated in schizophrenic patients. 7) Seizures: Seizures may occur with sertraline therapy: sertraline should be avoided in patients with unstable epilepsy and patients

with controlled epilepsy should be carefully monitored. 8) Suicide/suicidal thoughts/suicide attempts or clinical worsening: Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). 9) Paediatric population: Sertraline should not be used in the treatment of children and adolescents under the age of 18 years, except for patients with obsessive compulsive disorder aged 6-17 years old. 10) Warning while having Abnormal bleeding/Haemorrhage, Hyponatraemia, Hepatic impairment, Renal impairment, Diabetes, Electroconvulsive therapy, Grapefruit juice, Akathisia/psychomotor restlessness and Angle-Closure glaucoma. 11) Interference with urine screening tests: False-positive urine immunoassay screening tests for benzodiazepines have been reported in patients taking sertraline. 12) Withdrawal symptoms seen on discontinuation of sertraline treatment: Withdrawal symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt.

DRUG INTERACTIONS: ***Monoamine Oxidase Inhibitors***: Irreversible MAOIs (e.g. selegiline),

Reversible, selective MAO-A inhibitor (moclobemide), Reversible, non-selective MAOI (linezolid), Pimozide, ***Co-administration with sertraline is not recommended:*** CNS depressants and alcohol, serotonergic drugs, Drugs that Prolong the QT Interval, Lithium, Phenytoin, Triptans, Warfarin, Other drug interactions, digoxin, atenolol, cimetidine, ***Drugs affecting platelet function***: The risk of bleeding may be increased when medicines acting on platelet function (e.g. NSAIDs, acetylsalicylic acid and ticlopidine) or other medicines that might increase bleeding risk are concomitantly administered with SSRIs, including sertraline. ***Neuromuscular Blockers:*** SSRIs may reduce plasma cholinesterase activity resulting in a prolongation of the neuromuscular blocking action of mivacurium or other neuromuscular blockers, ***Drugs Metabolized by Cytochrome P450:*** Sertraline may act as a mild-moderate inhibitor of CYP 2D6. Chronic dosing with sertraline 50 mg daily showed moderate elevation (mean 23%-37%) of steady-state desipramine plasma levels (a marker of CYP 2D6 isozyme activity).

ADVERSE REACTIONS: Very Common (≥1/10): insomnia, dizziness, headache, somnolence, ejaculation failure, fatigue, **Common (≥1/100 to <1/10):** upper respiratory tract infection, pharyngitis, rhinitis, decreased appetite, increased appetite, anxiety, depression, agitation, libido decreased, nervousness, depersonalisation, nightmare, bruxism, tremor, movement disorders (including extrapyramidal symptoms such as hyperkinesia, hypertonia, dystonia, teeth grinding or gait abnormalities), paraesthesia, hypertonia, disturbance in attention, dysgeusia, visual disturbance, palpitations, tinnitus, hot flush, yawning, dyspepsia, constipation, abdominal pain, vomiting, flatulence, menstruation irregular, erectile dysfunction, malaise, chest pain, asthenia, pyrexia, weight increased. **Uncommon (≥1/1,000 to <1/100):** gastroenteritis, otitis media, neoplasm, hypersensitivity, seasonal allergy, neoplasm, mydriasis. **Rare (≥1/10,000 to <1/1,000):** diverticulitis, lymphadenopathy, thrombocytopenia, leukopenia, anaphylactoid reaction, hyperprolactinaemia, inappropriate antidiuretic, conversion disorder, paroniria, drug dependence, sleep walking, premature ejaculation, scotoma, glaucoma, diplopia, photophobia, hyphaemia, pupils unequal, vision abnormal, lacrimal disorder.

MARKETED BY:

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IN/SERTA 25, 50,100 mg/Oct-22/02/ABPI

(Additional information is available on request)