MedChoice CNS

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Sertraline

Zolodin

50 mg Tablet
ANTIDEPRESSANT

WARNING: Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders and those considering use of these agents "must balance risk with the clinical need".

FORMULATION:
Each tablet contains:
Sertraline (as hydrochloride)……50 mg

PRODUCT DESCRIPTION:
Sertraline (Zolodin) 50 mg tablet is a white, round, flat beveled edge with score on one side and plain on the other side.

CLINICAL PHARMACOLOGY
Pharmacodynamics:
The mechanism of action of Sertraline is presumed to be linked to its inhibition of CNS neuronal uptake of serotonin (5HT). It does not inhibit monoamine oxidase.
Pharmacokinetics:
Sertraline is slowly absorbed from the gastrointestinal tract with peak plasma concentration occurring about 4.5 to 8.5 hours after ingestion. It undergoes extensive first-pass metabolism in the liver. The main pathway is demethylation to N-desmethylsertraline which is inactive; further metabolism and glucuronide conjunction occur. Sertraline is widely distributed throughout body tissues and is highly bound (about 98%) to plasma proteins. The plasma elimination half-life of Sertraline is reported to be 24 to 26 hours. Sertraline is excreted in the urine and feces approximately in equal amounts, mainly as metabolites. Sertraline is distributed into breast milk.

INDICATION:
Sertraline HCl is used for the treatment of depression.

DOSAGE AND ADMINISTRATION:
Depression: Initial dose is 50 mg daily, if necessary, increments of 50 mg at intervals of at least a week to a maximum of 200 mg daily. It is taken orally.

PRECAUTIONS:
SSRIs (Selective Serotonin Reuptake Inhibitors) such as Sertraline (Zolodin) 50 mg Tablet should be used with caution and in reduced doses in elderly patients and to those with impaired renal or hepatic function. Caution should also be observed if the drug is to be used in patients with epilepsy or a history of such disorder, cardiac disease or a history of bleeding disorder, and in patients receiving concomitant electroconvulsive therapy (ECT). Patients should be closely monitored during early therapy until improvement in depression is observed because suicide is an inherent risk in depressed patients. Since SSRIs may impair performance of skilled tasks, patients are advised not to engage in activities such as driving or operating machinery.

CONTRAINDICATIONS:
Sertraline (Zolodin) 50 mg Tablet should not be given in patients with severe renal or hepatic failure and uncontrolled epilepsy. It should not generally be given to patients receiving Monoamine Oxidase Inhibitors (MAOIs) or for at least two weeks after their discontinuation.

ADVERSE EFFECTS:
Reported Adverse Effects include dry mouth and gastrointestinal disturbance (e.g. nausea, vomiting, dyspepsia, constipation and diarrhea. Anorexia and weight loss may also occur.
Neurological side effects: Anxiety, restlessness, nervousness, and insomnia, or drowsiness and fatigue; headache, tremor, dizziness, convulsions, hallucinations, extrapyramidal effects such as orofacial dystonias (teeth clenching) or dyskinesias (teeth grinding), sexual dysfunction, and symptoms suggestive of a serotonin syndrome.
Hematological side effects: Purpura and bruising have been reported as the most common adverse blood effects associated with this drug. Thrombocytopenia has also been reported.
Endocrine System side effects: Hyponatremia, hyperprolactinemia and galactorrhea have been reported.
Effect on eyes: Anisocoria (uneven pupillary dilation).
Others: Excessive sweating, pruritus, skin rashes and urticaria, angioedema, anaphylaxis, dyspnea, pulmonary fibrosis, arthralgia and myalgia.

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph.
Seek medical attention immediately at first sign of any adverse drug reaction."

PREGNANCY AND LACTATION:
Pregnancy Category C - Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Exposed neonates may develop complications requiring prolonged hospitalization, respiratory support, and tube feeding. Clinical reports have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, hypertonia, hyperreflexia, tremor, jitteriness, irritability, and constant crying.

DRUG INTERACTIONS:
Alcohol: Effects of alcohol may possibly be enhanced by SSRIs. Concomitant use of Sertraline (Zolodin) 50 mg Tablet and alcohol is not recommended.
Antibacterials: Concomitant use with Erythromycin may cause serotonin syndrome
Antidepressants: Severe adverse reactions including serotonin syndrome (e.g. agitation, ataxia, diaphoresis, diarrhea, fever, hyperreflexia, myoclonus, shivering and changes in mental status) may occur in patients receiving SSRI in combination with MAOIs. Sertraline should not be used in combination with a MAOI or within 14 days of discontinuing treatment with a MAOI.
Anticoagulant: SSRIs which include Sertraline (Zolodin) 50 mg Tablet may increase the coagulant activities of Warfarin
Antiepileptics: Sertraline (Zolodin) 50 mg Tablet may increase plasma concentration of Carbamazepine and Phenytoin.
Antimigraine drugs: SSRIs may also interact with serotonin (5-HT1) agonist with an increase risk of serotonin syndrome but it was concluded that most patients tolerate the combinations of Sumatriptan and an SSRI without incidence.
Antimuscarinic: Patients reported to have developed delirium while taking an antipsychotic, an SSRI, and Benzatropine.
Dopaminergics: Selegiline is an irreversible selective inhibitor of monoamine oxidase type B. Serious adverse effects have been reported when Selegiline and SSRIs have been used concomitantly, these reactions resemble the potential fatal serotonin syndrome. It is advised that SSRIs should not generally be given to patients receiving Selegiline, or for at least two weeks after it has been discontinued. Similarly at least two weeks should elapse between withdrawing an SSRI and starting Selegiline.
Gastrointestinal drugs: There is a risk for acute dystonia when coadministered with Metoclopramide.
Hypnotics: Isolated cases of visual hallucinations may occur when used concomitantly with this drug.
Opioid Analgesics: There is a possible risk when coadmistered with Tramadol or high doses of Oxycodone.
Thyroxine (Levothyroxine): The effects of Levothyroxine in hypothyroid patients may be decreased by concomitant administration with this drug and the dose of Levothyroxine may need to be increased.

DISCONTINUATION OF TREATMENT:
To avoid adverse events such as dysphoric mood, irritability, agitation, dizziness, sensory disturbances, anxiety, confusion, headache, lethargy, emotional liability, insomnia, and hypomania during discontinuation of treatment with Setraline (Zolodin) 50 mg Tablet, it is recommended to gradually reduce the dose than abrupt cessation whenever possible. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose but at a more gradual rate.

OVERDOSE AND MANAGEMENT:
Symptoms of overdose may include bradycardia, bundle branch block, coma, convulsions, delirium, hallucinations, hypertension, hypotension, manic reaction, pancreatitis, QT-interval prolongation, serotonin syndrome, stupor and syncope.

Treatment should consist of those general measures employed in the management of overdosage with any antidepressant.

Ensure an adequate airway, oxygenation and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion, or in symptomatic patients. Activated charcoal should be administered. Due to large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion and exchange transfusion are unlikely to be of benefit.

No specific antidotes for Sertraline are known.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:
Store at temperatures not exceeding 30ºC.

AVAILABILITY:
Sertraline (Zolodin) 50 mg Tablet……In Foil Strip of 10's (Box of 30's)

Registration No.: DRP - 7797
Date of First Authorization: June 2013
Date of Revision of Package Insert: July 2018

Manufactured for:
MEDCHOICE CNS PHARMA CORPORATION
Unit 1001, 88 Corporate Center, Valero corner
Sedeño Streets, Salcedo Village, Makati City

By:
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