Sermind® 25/50

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Sertraline Tablets BP 25/50 mg

SERMIND® 25
COMPOSITION:
Each Film Coated Tablet Contains:
Sertraline Hydrochloride BP
Eq. to Sertraline 25 mg
Excipients q.s.
Colour: Titanium Dioxide BP

SERMIND® 50
COMPOSITION:
Each Film Coated Tablet Contains:
Sertraline Hydrochloride BP
Eq. to Sertraline 50 mg
Excipients q.s.
Colour: Titanium Dioxide BP

DESCRIPTION:
SERMIND® 25/50 contains Sertraline is used to treat depression, obsessive-compulsive disorder, panic attacks, posttraumatic stress disorder and social anxiety disorder

PHARMACODYNAMICS:
Pharmacodynamic properties
Pharmacotherapeutic group: Selective serotonin reuptake inhibitors (SSRI), ATC code: N06 AB06
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.
Sertraline has not demonstrated potential for abuse. In a placebo-controlled, double-blind randomized study of the comparative abuse liability of sertraline, alprazolam and d-amphetamine in humans, sertraline did not produce positive subjective effects indicative of abuse potential.

Pharmacokinetic Properties
Absorption
In man, following an oral once-daily dosage of 50 to 200 mg for 14 days, peak plasma concentrations of sertraline occur at 4.5 to 8.4 hours after the daily administration of the drug. Food does not significantly change the bioavailability of sertraline tablets.
Distribution
Approximately 98% of the circulating drug is bound to plasma proteins.
Biotransformation
Sertraline undergoes extensive first-pass hepatic metabolism.
Based on clinical and in-vitro data, it can be concluded that sertraline is metabolized by multiple pathways including CYP3A4, CYP2C19 and CYP2B6. Sertraline and its major metabolite desmethylsertraline are also substrate of P-glycoprotein in-vitro.
Elimination
The mean half-life of sertraline is approximately 26 hours (range 22-36 hours). Consistent with the terminal elimination half-life, there is an approximately two-fold accumulation up to steady state concentrations, which are achieved after one week of once-daily dosing. The half-life of N-desmethylsertraline is in the range of 62 to 104 hours. Sertraline and N-desmethylsertraline are both extensively metabolized in man and the resultant metabolites excreted in faeces and urine in equal amounts. Only a small amount (<0.2%) of unchanged sertraline is excreted in the urine.

THERAPEUTIC INDICATIONS:
Sertraline Tablets is indicated for the treatment of:
- Major depressive episodes. Prevention of recurrence of major depressive episodes.
- Panic disorder, with or without agoraphobia
- Obsessive compulsive disorder (OCD) in adults and paediatric patients aged 6-17 years
- Social anxiety disorder.
- Post traumatic stress disorder (PTSD)

POSOLOGY AND METHOD OF ADMINISTRATION:
Posology:
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Therapy should be initiated at 25 mg/day. After one week, the dose should be increased to 50 mg once daily. This dosage regimen has been shown to reduce the frequency of early treatment emergent side effects characteristic of panic disorder.
Adults:
Depression and Obsessive Compulsive Disorder:
For depression and OCD, the usual effective dose is 50 mg/day. The daily dose may be increased in 50 mg increments and at intervals of at least one week over a period of weeks. The maximum recommended dose is 200 mg/day.
PTSD, Panic Disorder, Social Anxiety Disorder and Post Traumatic Stress Disorder:
The recommended dose is 25 mg daily increasing to 50 mg a day after one week. The daily dose then may be increased in 50 mg increments over a period of weeks. The maximum recommended dose is 200 mg/day.
Use in children and adolescents
Sertraline film-coated tablets must only be used to treat children and adolescents suffering from OCD aged 6-17 years old.
Obsessive Compulsive Disorder:
Children aged 6 to 12 years: the recommended starting dose is 25 mg daily. After one week, your doctor may increase this to 50 mg daily. The maximum dose is 200 mg daily.
Adolescents aged 13 to 17: the recommended starting dose is 50 mg daily. The maximum dose is 200 mg daily.
If you have liver or kidney problems, please tell your doctor and follow the doctor's instructions.
Method of administration
Sertraline tablets may be taken with or without food.
The tablets should not be chewed or crushed; they should always be swallowed whole, with a drink of water. Take your medicine once daily either in the morning or evening.

CONTRAINDICATION:
Hypersensitivity to the active substance or any of the excipients used in formulation.
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 contra-indicated

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Switching from Selective Serotonin Reuptake Inhibitors (SSRIs), antidepressants or anti-obsessional drugs:
There is limited controlled experience regarding the optimal timing of switching from SSRIs, antidepressants or anti-obsessional drugs to sertraline. Care and prudent medical judgement should be exercised when switching, particularly from long-acting agents such as fluoxetine.
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.
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.
Suicide / suicidal thoughts/suicide attempts:
Depression is associated with an increased risk of suicidal thoughts,self harm and suicide (suicide-related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs. It is general clinical experience that the risk of suicide may increase in the early stages of recovery.
Diabetes:
In patients with diabetes, treatment with an SSRI may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
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.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:
CNS depressants and alcohol: The coadministration of sertraline 200 mg daily did not potentiate the effects of alcohol, carbamazepine, haloperidol or phenytoin on cognitive and psychomotor performance in healthy subjects; however, the concomitant use of sertraline and alcohol is not recommended.
Lithium: In a placebo-controlled trial in normal volunteers, the co-administration of sertraline with lithium did not significantly alter lithium pharmacokinetics but did result in an increase in tremor relative to placebo, indicating a possible pharmacodynamic interaction. When co-administering sertraline with lithium patients should be appropriately monitored.
Phenytoin: A placebo-controlled trial in normal volunteers suggests that chronic administration of sertraline 200 mg/day does not produce clinically important inhibition of phenytoin metabolism. Nonetheless, as some case reports have emerged of high phenytoin exposure in patients using sertraline, it is recommended that plasma phenytoin concentrations be monitored following initiation of sertraline therapy, with appropriate adjustments to the phenytoin dose.
Triptans: There have been rare post-marketing reports describing patients with weakness, hyperreflexia, incoordination, confusion, anxiety and agitation following the use of sertraline and sumatriptan.
Warfarin: Co-administration of sertraline (200 mg daily) with warfarin resulted in a small but statistically significant increase in prothrombin time, which may in some rare cases unbalance the INR value. Accordingly, prothrombin time should be carefully monitored when sertraline therapy is initiated or stopped.
Other drug interactions, digoxin, atenolol, cimetidine: Co-administration with cimetidine caused a substantial decrease in sertraline clearance. The clinical significance of these changes is unknown. Sertraline had no effect on the beta-adrenergic blocking ability of atenolol. No interaction of sertraline 200 mg daily was observed with digoxin.
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

PREGNANCY AND LACTATION
Pregnancy:
Sertraline is not recommended in pregnancy, unless the clinical condition of the woman is such that the benefit of the treatment is expected to outweigh the potential risk.
Breast-feeding:
Sertraline levels in breast milk show that small quantities of sertraline and its metabolite N-desmethylsertraline are excreted in milk. Generally negligible to undetectable levels were found in infant serum, with one exception of an infant with serum levels about 50% of the maternal level (but without a noticeable health effect in this infant). To date, no adverse effects on the health of infants nursed by mothers using sertraline have been reported, but a risk cannot be excluded.
Fertility:
Human case reports with some SSRIs have shown that an effect on sperm quality is reversible.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
Sertraline has no effect on psychomotor performance. However, as psychotropic drugs may impair the mental or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery, the patient should be cautioned accordingly.

UNDESIRABLE EFFECTS:
Cardiovascular Blood pressure disturbances including postural hypotension, tachycardia.
Eye disorders Abnormal vision.
Gastro-intestinal Vomiting, abdominal pain.
Nervous system Amnesia, headache, drowsiness, movement disorders, paraesthesia, hypoaesthesia, depressive symptoms, hallucinations, aggressive reaction, agitation, anxiety, psychosis, depersonalisation, nervousness, panic reaction and signs and symptoms associated with serotonin syndrome which includes fever, rigidity, confusion, agitation, diaphoresis, tachycardia, hypertension and diarrhoea. There have also been reports of manic reaction, although this phenomenon may be part of the underlying disease.
Convulsions (Seizures) Sertraline should be discontinued in any patient who develops seizures.
Musculoskeletal Arthralgia, myalgia. Epidemiological studies, mainly conducted in patients 50 years of age and older, show an increased risk of bone fractures in patients receiving SSRIs and TCAs. The mechanism leading to this risk is unknown.
Hepatic/pancreatic Rarely, pancreatitis and serious liver events (including hepatitis, jaundice and liver failure). Asymptomatic elevations in serum transaminases (SGOT and SGPT) have been reported in association with sertraline administration (0.8 – 1.3%), with an increased risk associated with the 200mg daily dose. The abnormalities usually occurred within the first 1 to 9 weeks of drug treatment and promptly diminished upon drug discontinuation.
Renal & urinary disorders: Urinary retention.
Reproductive: Hyperprolactinemia, galactorrhoea, menstrual irregularities.
Skin and allergic reactions Rash (including rare reports of erythema multiform, photosensitivity), angioedema, ecchymosis, pruritus and anaphylactic reactions.
Metabolic Rare cases of hyponatremia have been reported and appeared to be reversible when sertraline was discontinued. Some cases were possibly due to the syndrome of inappropriate antidiuretic hormone secretion. The majority of reports were associated with older patients, and patients taking diuretics or other medications.
Hematologic There have been rare reports of altered platelet function and/or abnormal clinical laboratory results in patients taking sertraline. While there have been reports of thrombocytopenia, abnormal bleeding or purpura in several patients taking sertraline, it is unclear whether sertraline had a causative role.
General Malaise.
Other Withdrawal reactions have been reported with sertraline. Common symptoms include dizziness, paraesthesia, headache, anxiety and nausea. Abrupt discontinuation of treatment with sertraline should be avoided. The majority of symptoms experienced on withdrawal of sertraline are non-serious and self-limiting.

OVERDOSE
Toxicity
Sertraline Tablets has a margin of safety dependent on patient population and/or concomitant medication. Deaths have been reported involving overdoses of sertraline, alone or in combination with other drugs and/or alcohol. Therefore, any overdosage should be medically treated aggressively.
Symptoms
Symptoms of overdose include serotonin-mediated side effects such as somnolence, gastrointestinal disturbances (e.g nausea and vomiting), tachycardia, tremor, agitation and dizziness. Coma has been reported although less frequently.
Management
There are no specific antidotes to sertraline. It is recommended to establish and maintain an airway and, if necessary, ensure adequate oxygenation and ventilation. Activated charcoal, which may be used with a cathartic, may be as, or more effective than lavage, and should be considered in treating overdose. Induction of emesis is not recommended. Cardiac (e.g. ECG) and vital sign monitoring is also recommended, along with general symptomatic and supportive measures. Due to the large volume of distribution of sertraline, forced diuresis, dialysis, haemoperfusion and exchange transfusion are unlikely to be of benefit.

SHELF LIFE:
36 Months

PACKAGING
10 Tablets are packed in Alu-PVC Blister & such 3 Blisters are packed in printed carton along with pack insert.

STORAGE CONDITION:
Stored at a temperature not exceeding 30°C. Protect from light and moisture.
Keep the medicine out of reach of children.

Marketed by:

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