Trilion

[Sertraline]

50mg, 100mg Tablets

ٹرلیون

۵۰ ملی گرام، ۱۰۰ ملی گرام گولیاں

QUALITATIVE AND QUANTITATIVE COMPOSITION:
TRILION (Sertraline) is available for oral administration as:

1. **TRILION Tablet 50mg**
   Each film coated tablet contains:
   Sertraline as Sertraline HCl USP.....50mg
   (Product Specs.: USP)
2. **TRILION Tablet 100mg**
   Each film coated tablet contains:
   Sertraline as Sertraline HCl USP.....100mg
   (Product Specs.: USP)

CLINICAL PHARMACOLOGY:
Mechanism of Action:
Setraline 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. Setraline did not cause sedation and did not interfere with psychomotor performance.
Unlike tricyclic antidepressants, no weight gain is observed with sertraline treatment for depression or OCD. Some patients may experience a reduction of body weight with sertraline.
Pharmacokinetics:
In man, following oral once daily dosing over the range of 50 to 200mg/day for 14 days, peak plasma concentration (C_{max}) of sertraline occur at about 4.5 to 8.4 hours post dosing. Sertraline undergoes extensive first pass hepatic metabolism. The principal metabolite in plasma is N-desmethylsertraline. The half life of N-desmethylsertraline is in the range of 60-104 hours. Sertraline and N-desmethyl sertraline are both extensively metabolized in man and the resultant metabolites excreted in feaces and urine in equal amount. Only a small amount (<0.2%) of unchanged sertraline is excreted in the urine. Food does not significantly change the bioavailability of sertraline tablets.
Special Population:
Hepatic insufficiency:
A lower less frequent dose should be used in patients with hepatic impairment. Sertraline should not be used in cases of severe hepatic impairment .
INDICATIONS:
TRILION is indicated
- For the treatment of symptoms of depression, including depression accompanied by symptoms of anxiety, in patients with or without a history of mania.
- For the treatment of obsessive compulsive disorder (OCD).
- For the treatment of panic disorder, with, or without agoraphobia.
- For the treatment of post-traumatic stress disorder (PTSD).

DOSAGE AND METHOD OF ADMINISTARTION:
TRILION should be administered once daily, with or without food.
Initial treatment:
Depression and OCD-**TRILION** treatment should be started at a dose of 50mg/day.
Panic disorder and PTSD-Therapy should be initiated at 25mg/day. After one week the dose should be increased to 50mg once daily.
Titration:
Depression, OCD, panic disorder and PTSD patients not responding to a 50mg dose may benefit from dose increases. Dose changes should be made at intervals of at least one week, up to maximum of 200mg/day. Changes in dose should not be made more frequently than once per week given the 24 hour elimination half life of sertraline.
Maintenance dosage: Dosage during long term therapy should be kept at the lowest effective level, with subsequent adjustment depending on therapeutic response.
Special Population:
Use in children:
Pediatrics OCD patients (Aged 13 to 17):
Initially 50 mg once daily.
Pediatrics OCD Patients (Aged 6 To 12):
Initially 25mg/day, increasing to 50mg/day after one week.
Subsequent doses may be increased in case of lack of response in 50mg/day increments, up to 100mg/day as needed.
Titration in children and adolescents: sertraline has an elimination half life of approximately one day; dose changes should not occur at intervals of less than one week.
Use in elderly:
The same dosage as in younger patients may be used in the elderly.
CONTRAINDICATIONS:
TRILION is contraindicated in patients;
- With a history of hypersensitivity to sertraline.
- Concomitant use with monoamine oxidase inhibitors (MAOIs) & pimozide.

PRECAUTIONS:

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors.

Monoamine Oxidase Inhibitors (MAOIs): Cases of serious reactions, sometimes fatal have been reported in patients receiving sertraline in combination with Monoamine Oxidase Inhibitors (MAOIs), including the selective MAOI (selegiline) and the reversible MAOI (moclobemide).

Some cases presented with features resembling the serotonin syndrome, the symptoms of which include: hyperthermia, rigidity, myoclonus, autonomic instability with possible rigid fluctuations of vital signs, mental status changes. Therefore sertraline should not be used in combination with a MAOI or within 14 days of discontinuing treatment with MAOI.
Other Serotonergic Drugs: Co-administration of sertraline with other drugs which enhance serotonergic neurotransmission such as tryptophan or fenfluramine, should be undertaken with caution and avoided whenever possible due to the potential for pharmacodynamic interaction.
Switching from other Antidepressant and Anti-obsessional Drug: There is limited controlled experience regarding the optimal timing of switching from other 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.
Seizures:
Sertraline should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. Sertraline should be discontinued in any patient who develops seizures.
Withdrawal symptoms seen on discontinuation of sertraline:
Abrupt discontinuation should be avoided. When stopping treatment with sertraline the dose should be gradually reduced over a period of at least one to two weeks in order to reduce the risk of withdrawal reactions.
Effects on ability to drive and use machines:
As psychotropic drugs may impair the mental or physical abilities therefore caution should be advised when driving a car or operating machinery.
Pregnancy:
Sertraline should be used during pregnancy only if the benefit of the treatment is expected to outweigh the potential risk.
Nursing Mothers:
Use in nursing mothers is not recommended unless, in the judgement of the physician, the benefit out weighs the risk.

DRUG INTERACTIONS:
Drugs highly bound to plasma proteins:
Because sertraline is highly bound to plasma protein, the administration of sertraline hydrochloride to a patient taking another drug which is tightly bound to protein (e.g. warfarin) may cause a shift in plasma concentrations potentially resulting in an adverse effect.
Antiplatelet agents and anticoagulants:
The concurrent use of an antiplatelet agent (aspirin, clopidogrel) or anticoagulant (heparin, warfarin) with **TRILION** may potentiate the risk of bleeding. Caution should be exercised. For patients taking warfarin, carefully monitor the international normalized ratio.
Phenytoin:
TRILION may increase phenytoin concentrations. Monitor phenytoin levels when initiating or titrating **TRILION**. Reduce phenytoin dosage if needed.
Drugs metabolized by CYP2D6:
Sertraline is a CYP2D6 inhibitor. The dosage should be maintained accordingly. Example: flecainide, desipramine, dextromethorphan, metoprolol, nebivolol, venlafaxine
ADVERSE REACTIONS:
Common: Nausea diarrhea/loose stools, anorexia, dyspepsia, tremor, dizziness, insomnia, somnolence, increased sweating, dry mouth and sexual dysfunction (principally ejaculatory delay in males), vomiting, abdominal pain, movement disorders (such as extrapyramidal symptoms and gait abnormalities), convulsions, menstrual irregularities, hyperprolactinemia, galactorrhea, rash (including hepatitis, jaundice and liver failure).
OVERDOSAGE:
No specific therapy is recommended and there are no specific antidotes to sertraline.
Establish and maintain an airway and ensure adequate oxygen and ventilation if necessary, activated charcoal which may be used with the cathartic, may be used as more effective than lavage, and should be considered in treating overdose. Cardiac and vital signs monitoring is recommended along with general symptomatic and supportive measures. Due to the large volume of distribution of sertraline forced diuresis, dialysis, hemoperfusion and exchange transfusion are unlikely to be benefit.

INSTRUCTIONS:
- Store below 30°C
- Protect from light & moisture
- Keep out of reach of children

To be sold on prescription of a registered medical practitioner.

خوراک: ڈاکٹری ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

HOW SUPPLIED:
TRILION (Sertraline) 50mg Tablets are available in pack of 10's.
TRILION (Sertraline) 100mg Tablets are available in pack of 10's.

Manfactured By:
SIGMA PHARMA (International Private Limited.)
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