

Mudiral®

Sertraline Hydrochloride

Description: Mudiral® (Sertraline Hydrochloride) is a selective serotonin receptor inhibitor (SSRI) for oral administration.

Mode of action: Mudiral® (Sertraline Hydrochloride) is a selective serotonin reuptake inhibitor. Mudiral® helps correct the chemical imbalance of serotonin in the brain. The effectiveness of Mudiral® is presumed to be linked to its inhibition of CNS neuronal uptake of serotonin (5HT). Serotonin is a naturally occurring chemical in the brain that is involved in the transmission of messages between nerve cells.

Pharmacokinetics: Mudiral® (Sertraline Hydrochloride) undergoes extensive first pass metabolism. Following oral once-daily dosing over the range of 50 to 200 mg for 14 days, mean peak plasma concentrations (Cmax) of Mudiral (Sertraline Hydrochloride) occurred between 4.5 to 8.4 hours post-dosing. Sertraline is highly bound to serum proteins (98%).

Composition

Mudiral® 25 mg Tablet: Each tablet contains Sertraline Hydrochloride BP 28 mg equivalent to Sertraline 25 mg.

Mudiral® 50 mg Tablet: Each tablet contains Sertraline Hydrochloride BP 56 mg equivalent to Sertraline 50 mg.

Indication

Sertraline is indicated for

- Major Depressive Disorder
- Obsessive-Compulsive Disorder
- Panic Disorder
- Posttraumatic Stress Disorder
- Premenstrual Dysphoric Disorder
- Social Anxiety Disorder

Dosage & administration: Adult.

Major Depressive Disorder and Obsessive-Compulsive Disorder:

Treatment should be administered at a dose of 50 mg once daily.

Panic Disorder, Posttraumatic Stress Disorder and Social Anxiety Disorder:

Treatment should be initiated with a dose of 25 mg once daily. After one week, the dose should be increased to 50 mg once daily.

Premenstrual Dysphoric Disorder:

Treatment should be initiated with a dose of 50 mg/day, either daily throughout the menstrual cycle or limited to the luteal phase of the menstrual cycle, depending on physician assessment.

Children and adolescents:

Obsessive-Compulsive Disorder:

Treatment should be initiated with a dose of 25 mg once daily in children (ages 6-12) and at a dose of 50 mg once daily in adolescents (ages 13-17).

Contraindications

Mudiral® is contraindicated in patients with known hypersensitivity to any of the ingredients.

Use in pregnancy & lactation

In pregnancy: Mudiral® has been rated as Pregnancy category C. There was no evidence of teratogenicity at any dose level. There are no adequate and well controlled studies in pregnant women. Sertraline should be used during pregnancy only if the potential benefit justifies the potential risks to foetus.

In lactation: It is not known whether and if so in what amount, Mudiral® or its metabolites are excreted in human milk.

Side effects

Mudiral® is generally well tolerated. Tremor, dizziness, insomnia, fatigue, dry mouth and sexual problem may occur.

Precautions

Sertraline should be used in caution in pregnancy and lactation and in patients with epilepsy, impaired kidney or liver function.

Drug Interactions

MAO inhibitor, Diazepam, Tolbutamide or Cimetidine lead to changes in the behaviour of these substances in the body. During treatment with Sertraline patients must refrain from alcohol consumption.

Over dosage

Symptoms: Bradycardia, bundle branch block, coma, convulsions, delirium.

Management: Ensure an adequate airway, oxygenation and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended.

Storage

Store in a cool and dry place, protected from light.

Packaging

Mudiral® 25 mg Tablet: Each carton contains 10X5 tablets in blister pack.

Mudiral® 50 mg Tablet: Each carton contains 10X5 tablets in blister pack.



Manufactured by
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