Information For the User Sertraline 50mg Tablet

Sertalist 50 Tablet

Brand Name: Sertalist 50 Tablet

Dosage Form: Tablet

Therapeutic Category: Selective Serotonin Reuptake Inhibitor (SSRI) – Antidepressant

Composition:

Each uncoated tablet contains:

• Sertraline Hydrochloride I.P. equivalent to Sertraline 50 mg

• Excipients – q.s.

• Colour: Approved colour used

Pharmacology & Mechanism of Action:

Sertraline is a selective serotonin reuptake inhibitor (SSRI). It works by selectively inhibiting the reuptake of serotonin (5-HT) in the central nervous system, thereby enhancing serotonergic activity. This action helps in the management of depression and anxiety-related disorders by restoring the balance of serotonin in the brain.

Indications:

- Major depressive disorder (MDD)
- Obsessive-compulsive disorder (OCD)
- Panic disorder
- Social anxiety disorder
- Post-traumatic stress disorder (PTSD)
- Premenstrual dysphoric disorder (PMDD)

Dosage & Administration:

The recommended starting dose is 50 mg once daily, with or without food. The dose may be gradually increased in 50 mg increments at intervals of at least one week, based on patient response and tolerability. Maximum recommended dose is 200 mg per day. Dose adjustments should be made cautiously in elderly patients and those with hepatic impairment.

Contraindications:

Contraindicated in patients with known hypersensitivity to sertraline or any component of the formulation. Concurrent use with monoamine oxidase inhibitors (MAOIs), pimozide, or disulfiram is contraindicated due to risk of serious drug interactions.

Warnings & Precautions:

Use with caution in patients with a history of seizure disorder, bipolar disorder, or liver impairment. Monitor for suicidal ideation, especially in young adults and adolescents. Avoid abrupt discontinuation to prevent withdrawal symptoms. Patients should avoid alcohol while on therapy.

Drug Interactions:

Sertraline may interact with other serotonergic drugs increasing the risk of serotonin syndrome. CYP3A4 and CYP2D6 inhibitors or inducers may affect sertraline metabolism. Caution with NSAIDs and anticoagulants due to increased risk of bleeding.

Adverse Effects:

Common side effects include nausea, insomnia, dizziness, dry mouth, somnolence, and sexual dysfunction. Less common effects include increased sweating, agitation, tremor, and fatigue. Rare but serious adverse effects may include serotonin syndrome, hyponatremia, and seizures.

Overdose:

Symptoms may include agitation, tremors, seizures, tachycardia, nausea, and vomiting. Management is supportive and symptomatic as there is no specific antidote. Activated charcoal may be considered in recent ingestion.

Storage:

Store in a cool, dry place below 25°C. Protect from direct light and moisture. Keep out of reach of children.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

TM: Trademark Applied for