

Sertal Tablet

Composition : Sertraline HCl 25mg, 50mg & 100mg Tablet.

Indications : Sertal is indicated for the treatment of symptoms of depressive illness, including accompanying symptoms of anxiety. Following satisfactory response continuation with Sertal therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes, including accompanying symptoms of anxiety.

Dosage and administration : Dosage for Adult : Major Depressive Disorder and Obsessive-Compulsive Disorder-Sertal treatment should be administered at a dose of 50mg once daily. Panic Disorder, Posttraumatic Stress Disorder and Social Anxiety Disorder- Sertal treatment should be initiated with a dose of 25mg once daily. After one week, the dose should be increased to 50mg once daily. Premenstrual Dysphoric Disorder- Sertal treatment should be initiated with a dose of 50mg/day, either daily throughout the menstrual cycle or limited to the luteal phase of the menstrual cycle, depending on physician assessment.

Dosage for Pediatric Population : Sertal treatment should be initiated with a dose of 25mg once daily in children (ages 6-12) and at a dose of 50mg once daily in adolescents (ages 13-17). Sertal should be administered once daily, either in the morning or evening. Or as directed by the physician.

Side effects : The side effects are hypertension, tachycardia, dizziness, postural hypotension, peripheral edema, hypotension, leg cramps, pruritus, acne, dry skin, back pain, anemia etc.

Precautions : Use in patients with renal or hepatic impairment : As with many other medications, sertraline should be used with caution in patients with renal and hepatic impairment.

Use in Children : The use of Sertal in children is not recommended as safety and efficacy have not been established.

Use in the elderly : No special precautions are required. The usual adult dose is recommended. Several hundred elderly patients have participated in clinical studies with Sertal.

Contraindication : Sertal is contraindicated in patients with a known hypersensitivity to sertraline.

Drug interactions : Monoamine oxidase inhibitor : Sertal should not be used in combination with a MAOI or other centrally active medication. since Sertal is bound to plasma protein, the potential of Sertal to interact with other plasma protein bound drugs should be borne in mind. Co-administration of Sertal with warfarin resulted in a small but statistically significant increase in prothrombin time, the clinical significance of which is unknown. Accordingly prothrombin time should be carefully monitored when Sertal therapy is initiated or stopped.

Use in pregnancy and lactation : There are no adequate and well controlled studies in pregnant women, since animal reproduction studies are not always predictive of human response. Sertal should be used during pregnancy only if the perceived benefits outweigh the risks. Limited data concerning sertraline levels in breast milk are available, hence it is not recommended in nursing mother. Pregnancy Category **C** by FDA.

Packing : Each box contains

Sertal-25 : 5 x 10's tablets in blister pack.

Sertal-50 : 5 x 10's tablets in blister pack.

Sertal-100 : 3 x 10's tablets in blister pack.