

Tralin[®]

Sertraline

PRESENTATION: Tralin[®] 25: Each film-coated tablet contains Sertraline Hydrochloride INN equivalent to Sertraline 25mg. Tralin[®] 50: Each film-coated tablet contains Sertraline Hydrochloride INN equivalent to Sertraline 50mg. Tralin[®] 100: Each film-coated tablet contains Sertraline Hydrochloride INN equivalent to Sertraline 100 mg.

INDICATIONS: Major Depressive Disorder, Obsessive Compulsive Disorder (OCD), Panic Disorder, Posttraumatic Stress Disorder (PTSD), Premenstrual Dysphoric Disorder (PMDD), Social Anxiety Disorder.

DOSAGE AND ADMINISTRATION: Sertraline should be given as a single daily dose. Sertraline tablets can be administered with or without food. **ADULTS- Depression** (including accompanying symptoms of anxiety): The starting dose is 50mg daily. **Obsessive Compulsive Disorder:** The starting dose is 50mg daily, and the therapeutic dose range is 50-200mg daily. **Post-Traumatic Stress Disorder:** Initial dose is 25mg/day. After one week, the dose is 50mg once daily. Treatment should be withdrawn if there is no clear evidence of efficacy. **Depression** (including accompanying symptoms of anxiety), **OCD** and **PTSD:** In some patients doses higher than 50mg daily may be required. Over a period of weeks maximum dose may be 200mg daily. **Premenstrual Dysphoric Disorder:** 50mg/day, either daily throughout the menstrual cycle or limited to the luteal phase of the menstrual cycle, depending on physician assessment. **Social Anxiety Disorder:** 25mg once daily. After one week, the dose should be increased to 50mg once daily. **Panic Disorder:** 25mg once daily. After one week, the dose should be increased to 50mg once daily. **CHILDREN** (6-12) and **ADOLESCENTS** (13-17) - Specialists can initiate the administration of Sertraline to pediatric OCD patients (aged 13-17) at a dose of 50 mg/day. Therapy for pediatric OCD patients (aged 6-12) should commence at 25mg/day increasing to 50mg/day after 1 week. Subsequent doses may be increased in case of lack of response in 50mg/day increments up to 200mg/day as needed. Children aged less than six years: Not recommended. Use in the elderly: The usual adult dose is recommended. Sertraline tablets are for oral administration only. **HEPATICALLY IMPAIRED PATIENTS:** The use of sertraline in patients with liver disease should be approached with caution. The effects of sertraline in patients with moderate and severe hepatic impairment have not been studied. If sertraline is administered to patients with liver impairment, a lower or less frequent dose should be used.

CONTRAINDICATIONS: Sertraline is contra-indicated in patients with a known hypersensitivity to sertraline. Monoamine oxidase inhibitors: Cases of serious and sometimes fatal reactions have been reported in patients receiving an SSRI in combination with a monoamine oxidase inhibitor (MAOI). Sertraline may be started 14 days after discontinuing treatment with an irreversible MAOI. Use in hepatic impairment: There is insufficient clinical experience in patients with significant hepatic dysfunction and accordingly Sertraline should not be used in such patients.

PREGNANCY AND LACTATION: *Pregnancy:* Although animal studies did not provide any evidence of teratogenicity, the safety of Sertraline during human pregnancy has not been established. As with all drugs Sertraline should only be used in pregnancy if the potential benefits of treatment to the mother outweigh the possible risks to the developing foetus. *Lactation:* Sertraline is known to be excreted in breast milk. Its effects on the nursing infant have not yet been established. If treatment with Sertraline is considered necessary, discontinuation of breast-feeding should be considered.

SIDE EFFECTS: Side effects are nausea, diarrhea/loose stools, anorexia, dyspepsia, tremor, dizziness, insomnia, somnolence, increased sweating, dry mouth and sexual dysfunction (principally ejaculatory delay in males). In paediatric OCD patients, side-effects are headache, insomnia, agitation, anorexia, tremor. Most were of mild to moderate severity.

WARNINGS AND 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. Diabetes- In patients with diabetes, treatment with an SSRI may alter glycaemic control, possibly due to improvement of depressive symptoms. Seizures- The drug should be discontinued in any patient who develops seizures. Mania- Sertraline should be used with caution in patients with a history of mania/hypomania. Suicide- As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored during this period. Haemorrhage- There have been reports of cutaneous bleeding abnormalities such as ecchymoses and purpura with SSRIs. Caution is advised in patients taking SSRIs. Use in the elderly- The pattern and incidence of adverse reactions in the elderly is similar to that in younger patients. Use in Children- The efficacy of Sertraline in pediatric patients with depression or panic disorder has not been demonstrated in controlled trials. Safety and effectiveness in pediatric patients below the age of 6 have not been established.

DRUG INTERACTIONS: 1) Potentially hazardous interaction with Monoamine Oxidase Inhibitors, oral anticoagulants, CNS-active drugs, alcohol, hypoglycemic drugs. 2) Other significant interactions with atenolol, electroconvulsive therapy, cimetidine, lithium.

PACKAGING QUANTITIES: Tralin[®] 25: Box containing 100's tablets in blister pack, Tralin[®] 50: Box containing 50's tablets in blister pack, Tralin[®] 100: Box containing 50's tablets in blister pack.

Manufactured by :
 **Silva**
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