xxxxxxxx-5253

SERENATA TABLETS 100 mg
SERENATA TABLETS 50 mg

Serenata Tablet 50mg: Sertraline Hydrochloride equivalent to Sertraline 50mg.
White to off white capsule shaped, biconvex film coated tablets with bisecting line on one side
(Thickness 3.1 ± 0.2mm and size/dimension 10.5mm x 4.3mm).
Serenata Tablet 100mg: Sertraline Hydrochloride equivalent to Sertraline 100mg.
White to off white capsule shaped, biconvex film coated tablets, with bisecting line on one side (Thickness 4.0 ± 0.2mm and size/dimension 13.3mm x 5.4mm).

PHARMACODYNAMIC

Sertraline is a potent and specific inhibitor of neuronal serotonin (5-HT) uptake in vitro and in vivo, but is without affinity for muscarinic, serotonergic, dopaminergic, adrenergic, histaminergic, GABA or benzodiazepine receptors.
Sertraline is devoid of stimulant, sedative or anticholinergic activity or cardiotoxicity in animals.
Unlike tricyclic antidepressants, no weight gain is observed with sertraline treatment for depression.
Sertraline has not been observed to produce physical or psychological dependence.

PHARMACOKINETICS:

Sertraline exhibits dose proportional pharmacokinetics over the range of 50 to 200mg.
After oral administration of sertraline in man, peak blood levels occur within 4.5 to 8.4 hours. Daily doses of sertraline achieve steady-state after one week. Sertraline has a plasma half-life of approximately 26 hours with a mean half-life for young and elderly adults ranging from 22 to 36 hours. Sertraline is approximately 98% is bound to plasma proteins. The principle metabolite, N- desmethylsertraline, is inactive in in-vivo models of depression and has a half-life of approximately 62 to 104 hours. Sertraline and N-desmethylsertraline are both extensively metabolized in man and the resultant metabolites excreted in faeces and urine in equal amounts. Only a small amount (<0.2%) of unchanged sertraline is excreted in the urine.
The pharmacokinetic of Sertraline in paediatric OCD patients have been shown to be comparable with adults, although peadiatric patients metabolise sertraline with slightly higher efficiency. However, lower doses may be advisable for paediatric patients given their lower body weights (especially 6-12 years), in order to avoid excessive plasma levels.
A clear relationship between sertraline concentration and the magnitude of therapeutic response has not been established.
The pharmacokinetics of sertraline in elderly patients are similar to younger adults.
Food does not significantly change the bioavailability of sertraline.

INDICATION:

Sertraline is indicated for the treatment of symptoms of depression, including accompanied by symptoms of anxiety, in patients with or without a history of mania.
Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes including accompanying symptoms of anxiety.
Sertraline is indicated for the treatment of obsessive-compulsive disorder (OCD).
Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of OCD.
Sertraline is indicated for the treatment of post-traumatic stress disorder (PTSD).
Following satisfactory response, continuation with sertraline therapy is effective in preventing relapse of the initial episode of PTSD.

RECOMMENDED DOSAGE

Sertraline tablets should be given as a single daily dose; administered with or without food.

Adults

DEPRESSION (including accompanying symptoms of anxiety)

Sertraline treatment is initiated at a dose of 50 mg once daily. The usual antidepressant dose is 50 mg daily; however some patients may require higher doses.

OBSESSIVE COMPULSIVE DISORDER (OCD)

The starting dose of sertraline is 50 mg once daily. The therapeutic dose range is 50 to 200 mg daily.

POST-TRAUMATIC STRESS DISORDER (PTSD)

Treatment of patients with PTSD should be initiated with a dose of 25 mg per day. After one week, the daily dose should be increased to 50 mg. Dosing should be periodically reviewed for response as PTSD is a heterogeneous condition and some patients meeting the criteria of PTSD may not appear to be responsive to sertraline therapy. The treatment should be withdrawn if there is no clear evidence of efficacy.

DEPRESSION (including accompanying symptoms of anxiety), OCD AND PTSD

Some patients may require daily doses higher than 50 mg. For patients showing an incomplete response but good toleration to lower doses, dosage adjustments should be made in 50 mg increments over a period of weeks, up to a maximum of 200 mg daily.
After achieving the optimal therapeutic response the dose should be reduced, depending on therapeutic response, to the lowest effective level. Patients requiring prolonged maintenance therapy should be maintained at the lowest effective level with subsequent adjustments depending on the therapeutic response to the treatment. The onset of the therapeutic effect of sertraline may be seen within 7 days, although it usually takes 2 to 4 weeks (and even longer in OCD) to obtain full activity. In case of therapeutic trial in PTSD a longer treatment period (beyond 12 weeks in some cases) may be required.

Use in children

The safety and effectiveness of sertraline in children have not been fully 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 sertraline The incidence and pattern of adverse reactions in the elderly population is similar to that in younger patients.
Sertraline tablets are only for oral administration.

CONTRAINDICATION:

Sertraline tablets are contraindicated 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), including the selective MAOI selegiline and the reversible MAOI (RIMA) moclobemide and in patients who have recently discontinued an SSRI and have been started on a MAOI.
Some cases presented with features resembling serotonin syndrome. Symptoms of a drug interaction with a MAOI include hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of the vital signs, mental status changes that include confusion, irritability and extreme agitation progressing to delirium and coma.
Sertraline should not be used in combination with a MAOI. Sertraline may be started 14 days after discontinuing treatment with an irreversible MAOI and at least one day after discontinuing treatment with the reversible MAOI (RIMA) moclobemide. At minimum a period of 14 days should elapse after discontinuing sertraline treatment before starting a MAOI or RIMA.

USE IN HEPATIC IMPAIRMENT

There is insufficient clinical experience available in patients with significant hepatic dysfunction and therefore sertraline should not be used in such patients.
Concomitant use of sertraline in patients receiving pimozide is contraindicated; see Interaction with other medicaments and other forms of interaction.
Sertraline should not be used in children and adolescents under the age of 18 years with major depressive disorder.

WARNINGS & PRECAUTION:

MONOAMINE OXIDASE INHIBITORS

See Contraindications.

USE IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT

Sertraline should be used with caution in patients with renal and hepatic impairment *(see also Contraindications).*
Sertraline is extensively metabolized and hence urinary excretion of unchanged drug is a minor route of elimination. Single dose pharmacokinetic parameters in patients with mild to moderate or severe renal impairment (creatinine clearance 20-50 ml/min and less than 20 ml/min, respectively) were not significantly different compared with control. However, steady state pharmacokinetics of sertraline have not been adequately studied in this patient population and sertraline tablets should be used with caution when treating patients with renal impairment.
Sertraline is extensively metabolized by the liver. In patients with mild, stable cirrhosis a prolongation in the elimination half life and about a three fold increase in Cmax and AUC was observed in comparison with normal subjects during a multiple dose pharmacokinetic study. There were no significant differences observed in plasma protein binding between the two groups. The use of sertraline in patients with hepatic disease should be approached with caution; a lower or less frequent dose should be used in patients with hepatic impairment.

DIABETES

Treatment with an SSRI in patients with diabetes may alter the glycaemic control, possibly due to improvement of depressive symptoms. Dosage of insulin and/or oral hypoglycaemic drugs may need to be adjusted.

SEIZURES

Seizures are a potential risk with antidepressant and antiobsessional drugs. The drug should be discontinued in any patient who develops seizures. Sertraline should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. Sertraline should be discontinued if an increase in seizure frequency occurs.

ELECTROCONVULSIVE THERAPY (ECT)

Since there is little clinical experience of concurrent administration of sertraline and ECT, caution is advisable.

MANIA

Sertraline should be used with caution in patients with a history of mania/hypomania and therapy should be discontinued in any patient entering a manic phase.

SUICIDAL TENDENCIES

The possibility of a suicidal attempt is inherent in depression and may persist until significant therapeutic effect is achieved. Since improvement may not occur in the first few weeks or more of treatment, patients should be closely monitored during this period. General clinical experience with all antidepressants suggests that the risk of suicide may increase in the early stages of recovery.

HAEMORRHAGE

There have been reports of cutaneous bleeding abnormalities such as purpura and ecchymoses with SSRIs.
Caution is advised in patients on SSRI therapy, particularly in concomitant administration with drugs known to affect platelet function e.g. atypical antipsychotics and phenothiazines, most tricyclic antidepressants, aspirin and non-steroidal anti-inflammatory drugs (NSAIDs); also in patients with a history of bleeding disorders.

USE IN THE ELDERLY

The incidence and pattern of adverse reaction in the elderly population is similar to that in younger patients.

USE IN CHILDREN

Use in children

The safety and effectiveness of sertraline in children have not been fully established.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Clinical pharmacology studies have shown that sertraline has no effect on psychomotor performance. However as antidepressant or anti-obsessional drugs may impair the abilities required for performing potentially hazardous tasks such as driving a car or operating machinery, patients should be cautioned accordingly. Sertraline should not be administered with benzodiazepines or other tranquillizers in patients who drive or operate machinery.

Suicidality in children and adolescents:

Antidepressants increase the risk of suicidal thinking and behaviour (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
Anyone considering the use of antidepressants in a child or adolescent for any clinical use must balance the risk of increased suicidality with clinical need.
Patients who have started on therapy should be observed closely for clinical worsening, suicidality or unusual changes in behaviour.
Families and caregivers should be advised to closely observe the patients and to communicate with the prescriber.
This product is not recommended for any pediatric indication.

Sexual dysfunction

Selective serotonin reuptake inhibitors (SSRIs)/serotonin norepinephrine reuptake inhibitors (SNRIs) may cause symptoms of sexual dysfunction. There have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of SSRIs/SNRIs.

INTERACTION WITH OTHER MEDICAMENTS:

MONOAMINE OXIDASE INHIBITORS

See Contraindications.

CENTRALLY ACTIVE MEDICATION

Sertraline should be used with caution when administered with other centrally active medication. In particular, SSRIs have the potential to interact with tricyclic antidepressants leading to an increase in plasma levels of the tricyclic antidepressant. A possible mechanism for this interaction is the inhibitory effect of SSRIs on the CYP2D6 isoenzyme. There is variability among SSRIs in the extent to which they inhibit the activity of CYP2D6. The clinical significance of this interaction depends on the degree of inhibition and the therapeutic index of the co-administered drug. In formal interaction studies chronic dosing with sertraline 50 mg daily showed minimal increase (mean 23-37%) of steady state plasma desipramine levels (a marker of CYP2D6 activity).
Pimozide: Increased pimozide levels have been demonstrated in a study with single low dose pimozide (2 mg) with co-administered sertraline. The increase in pimozide levels were not linked to any changes in ECG. The mechanism of this interaction is not known but due to the narrow therapeutic index of pimozide, concomitant use of sertraline and pimozide is contraindicated.

ALCOHOL

No adverse effect was found on cognitive or psychomotor performance (relative to placebo) when healthy subjects taking 200 mg sertraline per day for 9 days were given a single dose of 550 mg/kg alcohol. However, concomitant use of sertraline and alcohol in depressed patients is not recommended.

LITHIUM AND TRYPTOPHAN

Co-administration of sertraline and lithium did not significantly alter lithium pharmacokinetics (in a placebo controlled trial in normal volunteers).
However, co-administration of sertraline with lithium did result in increase in tremor relative to placebo, indicating a possible pharmacodynamic interaction. There have been other reports of enhanced effects when SSRIs have been given with lithium or tryptophan and therefore the concomitant use of SSRIs with these drugs should be undertaken with caution.

SEROTONERGIC DRUGS

There is limited controlled experience regarding optimal timing of switching from other antidepressant or antiobsessional drugs to sertraline. Care and prudent medical judgement should be exercised when switching, particularly from long-acting agents. The duration of washout period which should intervene before switching from one selective serotonin reuptake inhibitor (SSRI) to another has not been established.
Until further data available, serotonergic drugs, such as tramadol, sumatriptan or fenfluramine, should not be used concomitantly with sertraline, due to a possible enhancement of 5-HT associated effects.

ST JOHN'S WORT (Hypericum perforatum)

Since there is a possibility of serotonergic potentiation, concomitant use of herbal remedy St John's wort in patients receiving SSRIs should be avoided.

DRUGS THAT AFFECT PLATELET FUNCTION, SUCH AS NSAIDs

See Special warnings and special precautions for use (haemorrhage).

OTHER DRUG INTERACTIONS

Sertraline is bound to plasma proteins; the potential of interaction with other plasma protein bound drugs should be borne in mind.
Formal drug interaction studies that have been performed with sertraline are as follows: -
Co-administration of sertraline (200 mg daily) with diazepam or tolbutamide resulted in small but statistically significant changes in some pharmacokinetic parameters.
Co-administration with cimetidine caused a substantial decrease in the sertraline clearance. The clinical significance of these changes is unknown.
Sertraline had no effect on beta-adrenergic blocking ability of atenolol.
No interaction was observed between sertraline and glibenclamide or digoxin.
Co-administration of sertraline with warfarin caused a small yet statistically significant increase in prothrombin time; the clinical significance of this effect is unknown. Therefore, prothrombin time should be monitored carefully when sertraline therapy is initiated or terminated.
Sertraline (200 mg daily) did not potentiate the effects of carbamazepine, haloperidol or phenytoin on cognitive and psychomotor performance in healthy subjects.

PREGNANCY & LACTATION:

Use in pregnancy: Although animal studies did not provide any evidence of teratogenicity, the safety of sertraline during human pregnancy has not been established. Sertraline should be used during pregnancy only if the potential benefits of the treatment to the mother outweigh the possible risks to the developing foetus.
Use in Lactation: Sertraline is known to be excreted in breast milk; its effects on the nursing infants have not been established. If treatment with sertraline is considered necessary, discontinuation of breast feeding should be considered.
Observational data indicate an increased risk (less than 2-fold) of postpartum haemorrhage following SSRI/SNRI exposure within the month prior to birth.

SIDE EFFECTS:

The following side-effects were reported in published clinical trials which occurred significantly more frequently with sertraline than placebo in multiple dose studies were nausea, diarrhoea/ loose stools, anorexia, dyspepsia, tremor, dizziness, insomnia, somnolence, increased sweating, dry mouth and sexual dysfunction (primarily delayed ejaculation in males).
The side-effects profile commonly observed in double-blind, placebo-controlled studies in patients with OCD and PTSD was similar to that observed in patients with depression.
In paediatric patients with OCD the following side-effects occurred significantly more frequently with sertraline than placebo: headache, insomnia, agitation, anorexia, tremor. Most of those side effects were of mild to moderate severity.
Post marketing spontaneously reports have included the following side-effects:
Cardiovascular: Blood pressure disturbances including postural hypotension, tachycardia.
Eye Disorders: Abnormal vision.
Gastro-intestinal: vomiting, abdominal pain.
Nervous system: amnesia, heahache, drowsiness, movement disorders, paraesthesia, hypoaesthesia, depressive symptoms, hallucinations, aggressive reaction, agitation, anxiety, psychosis, depersonalisation, nervousness, panic reaction and signs and symptoms associated with serotonin syndrome which include fever, rigidity, confusion, agitation, diaphoresis, tachycardia, hypertension and diarrhoea.
There have been reports of manic reaction; although this phenomenon may be part of the underlying disease.
Convulsion (seizures): Sertraline should be discontinued in any patients who develops seizures.
Musculoskeletal: Arthralgia, myalgia.
Hepatic/ pancreactic: Rare reports of pancreatitis and serious liver events (including hepatitis, jaundice and liver failure). Asymptomatic elevations in serum transaminases (SGOT and SGPT) have been reported in association with sertraline administration (0.8-1.3%); with an increased risk associated with the 200mg daily dose. The abnormalities usually occurred within the first 1 to 9 weeks of drug treatment and promptly diminished upon drug discontinuation.
Renal & urinary disorders: Urinary retention.
Reproductive disorders: Hyperprolactinemia, galactorrhoea, menstrual irregularities, anorgasmy.
Skin and allergic reactions: Rash (including rare reports of erythema multiforme, photosensitivity), angioedema, ecchymoses, pruritus and anaphylactoid reactions.
Metabolic: There have been rare reports of hyponatremia, which appeared to be reversible when sertraline was discontinued. Some cases were possibly due to the syndrome of inappropriate antidiuretic hormone secretion. The majority of reports were associated with older patients, and patients taking diuretics or other medications.
Haematologic: There have been rare reports of altered platelet function and/or abnormal clinical laboratory results in patients taking sertraline. While there have been reports of thrombocytopenia, abnormal bleeding or purpura in several patients taking sertraline it is not clear whether sertraline had a causative role.
General: Malaise.
Other: There have been reports of withdrawal reactions with sertraline. Common symptoms included dizziness, paraesthesia, headache, anxiety and nausea. Abrupt discontinuation of treatment with sertraline should be avoided. The majority of symptoms experienced on withdrawal are non-serious and self-limiting.

OVERDOSE AND TREATMENT

On the evidence available sertraline has a wide margin of safety in overdose with overdoses of sertraline alone up to 8 g having been reported. Deaths involving overdoses of sertraline in combination with other drugs and/or alcohol have been reported; therefore any overdosage should be treated aggressively.
Symptoms of overdose include serotonin-mediated side-effects like somnolence, gastrointestinal disturbances (such as nausea and vomiting), tachycardia, tremor, agitation and dizziness. Less frequently reported was coma.
No specific therapy is recommended and there are no specific antidotes to sertraline. Establish and maintain an airway, ensure adequate oxygenation and ventilation. Activated charcoal, which may be used with sorbitol, may be as or more effective than emesis or lavage, and should be considered in treating overdose. It is recommended monitoring cardiac and vital signs along with general and symptomatic measures. Due to the large volume of distribution of sertraline, forced diuresis, dialysis, haemoperfusion and exchange transfusion are unlikely to be of benefit.

STORAGE: Store below 30^{o}C.

PRESENTATION: Each blister contains 10 tablets. The blister strips are packed in printed cartons containing a total of 30 tablets (3 strips of 10).

DATE OF REVISION OF PACKAGE INSERT
3rd November 2025

torrent PHARMA

MANUFACTURER :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.

PRODUCT NAME : Serenata Tablet	**COUNTRY :** Malaysia	**LOCATION :** Chhatral	**Supersedes A/W No.:**			
ITEM / PACK : Insert	**NO. OF COLORS:** 1	**REMARK : Folded Size 35 mm**				
DESIGN STYLE : Front-Back	**PANTONE SHADE NOS.:**	**SUBSTRATE :**				
CODE : xxxxxxxxxx-5253	Black	**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM) : 150 x 315		Prepared By	**Pkg.Dev**			
ART WORK SIZE : S/S		Reviewed By	**Pkg.Dev**			
DATE : 07-11-2025		Approved By	**Quality**			