ELLETRA

COMPOSITION:

Ellettra 50mg Tablets
Each tablet contains:
Sertraline (as HCl) M.S. 50mg
Ellettra 100mg Tablets
Each tablet contains:
Sertraline (as HCl) M.S. 100mg
Product conforms to the Manufacturer's Specifications.

DESCRIPTION:

Sertraline Hydrochloride (Ellettra) is a selective Serotonin reuptake inhibitor (SSRI) for oral administration. It has a molecular weight of 342.7. Sertraline Hydrochloride is (1S-cis)-4-(3, 4-dichlorophenyl)-1, 2, 3, 4-tetrahydro-N-methyl-1-naphthalenamine Hydrochloride. The empirical formula C17H17NCl2•HCl.
Sertraline Hydrochloride is a white crystalline powder that is slightly soluble in water and isopropyl alcohol and sparingly soluble in ethanol.

MECHANISM OF ACTION:

Sertraline is a potent and specific inhibitor of neuronal Serotonin (5-HT) uptake in vitro which results in the potentiation of the effects of 5-HT. It has very weak effects on Norepinephrine and Dopamine neuronal reuptake. At clinical doses, Sertraline blocks the uptake of Serotonin into human platelets. It is devoid of stimulant, sedative or anticholinergic activity or cardiotoxicity. In controlled studies in normal volunteers, Sertraline did not cause sedation and did not interfere with psychomotor performance. In accordance with its selective inhibition of 5-HT uptake, Sertraline does not enhance catecholenergic activity. Sertraline has no affinity for Muscarinic (Cholinergic) Serotonergic, Dopaminergic, Adrenergic, Histaminergic, GABA or Benzodiazepine receptors.

PHARMACOKINETICS:

Following oral once daily dosing over the range of 50 to 200 mg for 14 days, peak plasma concentrations (Cmax) of Sertraline Hydrochloride(Ellettra) occur at about 4.5 to 8.4 hours post dosing. The pharmacokinetic profile in either adolescents or the elderly is not significantly different from that in adults between 18 and 65 years. The mean half life of Sertraline for young and elderly men and women ranges from 22-36 hours. Approximately 98% of the circulating drug is bound to plasma proteins. Sertraline undergoes extensive first pass hepatic metabolism. Only a small amount (<0.2%) of unchanged Sertraline Hydrochloride(Ellettra) is excreted in the urine. Food does not significantly change the bioavailability of Sertraline Hydrochloride(Ellettra) tablets.

INDICATIONS:

Sertraline Hydrochloride (Ellettra) is indicated for the treatment of symptoms of depression, including depression accompanied by symptoms of anxiety, in patients with or without a history of mania. Following satisfactory response, continuation with Sertraline Hydrochloride (Ellettra) therapy is effective in preventing relapse of the initial episode of depression or recurrence of further depressive episodes.
Sertraline Hydrochloride (Ellettra) is also indicated for the treatment of obsessive compulsive disorder (OCD): Following initial response, Sertraline Hydrochloride(Ellettra) has been associated with

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sustained efficacy, safety and tolerability in upto 2 years of treatment of OCD.

DOSAGE & ADMINISTRATION:

Sertraline Hydrochloride(Ellettra) should be administered once daily, either in the morning or evening. Sertraline Hydrochloride (Ellettra) tablets can be administered with or without food. The usual therapeutic dose is 50mg/day. This dose may be increased. In case of lack of response in 50mg/day increments to a maximum of 200mg/day over a period of two weeks. The onset of therapeutic effect may be seen within 7 days; however, for full activity 2 to 4 weeks and even longer (in OCD) are usually necessary.

Use in Children:

The safety and effectiveness of Sertraline Hydrochloride(Ellettra) in children have not been fully established.

Use in Elderly:

The same dose range as in younger patients may be used in the elderly.

CONTRAINDICATIONS:

The use of Monoamine Oxidase Inhibitors (MAOI) is intended to treat psychiatric disorders with Sertraline Hydrochloride (Ellettra) or within 14 days of stopping treatment with Sertraline Hydrochloride (Ellettra) is contraindicated because of an increased risk of Serotonin Syndrome. The use of Sertraline Hydrochloride (Ellettra) within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated.

Starting Sertraline Hydrochloride (Ellettra) in a patient who is being treated with MAOIs such as Linezolid or intravenous Methylene blue is also contraindicated because of an increased risk of Serotonin Syndrome.

Concomitant use in patients taking Pimozide is contraindicated.

Sertraline Hydrochloride (Ellettra) is contraindicated in patients with a hypersensitivity to Sertraline or any of the inactive ingredients in Sertraline Hydrochloride (Ellettra).

PRECAUTIONS:

Monoamine Oxidase Inhibitors: Cases of serious reactions, sometimes fatal have been reported in patients receiving Sertraline Hydrochloride(Ellettra) in combination with a Monoamine Oxidase Inhibitor (MAOI), including the selective MAOI, Sertraline Hydrochloride(Ellettra) should not be used in combination with an MAOI or within 14 days of discontinuing treatment with an MAOI. Similarly, atleast 14 days should elapse after discontinuing Sertraline Hydrochloride (Ellettra) treatment before starting an MAOI therapy.

Other Serotonergic drugs:

Coadministration of Sertraline Hydrochloride (Ellettra) with other drugs which enhance Serotonergic neurotransmission, such as Tryptophan or Fenfluramine should be undertaken with caution and avoided whenever possible due to the potential for pharmacodynamic interaction.

Seizures:

Seizures patients are at potential risk with antidepressant and antiobsessional drugs. Sertraline Hydrochloride (Ellettra) should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. Sertraline Hydrochloride (Ellettra) should be discontinued in any patient who develops seizures.

Use in Hepatic Insufficiency:

The use of Sertraline Hydrochloride (Ellettra) in patients with hepatic disease must be approached

ing overdoses of Sertraline Hydrochloride (Ellettra), primarily in combination with other drugs and/or Alcohol. Therefore, any overdosage should be medically treated aggressively.
Symptoms:
Symptoms of overdose include Serotonin mediated side effects such as somnolence, gastrointestinal disturbances (such as nausea and vomiting), tachycardia, tremor, agitation and dizziness. Less frequently reported was coma.
Treatment:
There are no specific Antidotes to Sertraline Hydrochloride (Ellettra). Establish and maintain an airway and ensure adequate oxygenation and ventilation. Activated Charcoal, which may be used with a cathartic, may be as or more effective than lavage and should be considered in treating overdose. Induction of emesis is not recommended. Due to the large volume of distribution of Sertraline, forced diuresis, dialysis, haemoperfusion and exchange transfusion are unlikely to be of benefit.
Sertraline Hydrochloride (Ellettra) overdose may prolong the QT interval and ECG monitoring is recommended in all ingestions of Sertraline Hydrochloride (Ellettra) overdoses.

STORAGE:

Store in a cool & dry place below 25OC.
Protect from light, heat & moisture.
Keep out of reach of children.

PRESENTATION:

Ellettra 50mg tablets are available in a blister pack of 30’s
Ellettra 100mg tablets are available in a blister pack of 20’s

with caution. If Sertraline Hydrochloride (Ellettra) is administered to patients with hepatic impairment, a lower or less frequent dose should be considered.
Use in Renal Insufficiency:
Since Sertraline Hydrochloride (Ellettra) is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Sertraline Hydrochloride (Ellettra) dosing does not have to be adjusted based on the degree of renal impairment.

PREGNANCY AND LACTATION:

Pregnancy:
There are no adequate and well controlled studies in pregnant women. Sertraline Hydrochloride (Ellettra) should be used druing pregnancy only if the perceived benefits outweigh the risks.
Lactation:
Use in nursing mothers is not recommended unless in the judgement of the physician, the benefit out weight the risk.

DRUG-DRUG INTERACTION:

CNS Depressants and Alcohol:
The coadministration of Sertraline Hydrochloride (Ellettra) 200 mg daily did not potentiate the effects of Alcohol, Carbamazepine, Haloperidol or Phenytoin on cognitive and psychomotor performance, in healthy subjects.
Protein bound Drugs:
Since Sertraline Hydrochloride (Ellettra) is bound to plasma proteins, the potential of Sertraline Hydrochloride (Ellettra) to interact with other plasma protein bound drugs should be borne in mind.
Other Drug Interactions:
Formal drug interaction studies have been performed with Sertraline Hydrochloride (Ellettra). Coadministration of Sertraline Hydrochloride (Ellettra) 200 mg daily with Diazepam or Tolbutamide resulted in small statistically significant changes in some pharmacokinetic parameters. Coadministration with Cimetidine caused a substantial decrease in Sertraline Hydrochloride (Ellettra) clearance. The clinical significance of these changes is unknown. Sertraline Hydrochloride (Ellettra) has no effect on the beta adrenergic blocking ability of Atenolol. No interaction of Sertraline Hydrochloride (Ellettra) 200 mg daily was observed with Glibenclamide or Digoxin.
Warfarin:
Coadministration of Sertraline Hydrochloride (Ellettra) 200 mg daily 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 Sertraline Hydrochloride (Ellettra) therapy is initiated or stopped.

ADVERSE DRUG REACTIONS:

Side effects which occurred significantly more frequently with Sertraline Hydrochloride (Ellettra) are nausea, diarrhoea/loose stools, anorexia, dyspepsia, tremor, dizziness, insomnia, somnolence, increased sweating, dry mouth and sexual dysfunction (principally ejaculatory delay in males).

OVER DOSAGE:

Toxicity:
Sertraline Hydrochloride (Ellettra) has a wide margin of safety in overdose. Overdoses of Sertraline Hydrochloride (Ellettra) alone of up to 13.5 g have been reported. Deaths have been reported involv