113 mm

245 mm

SERTRALINE HCl

SERNADE®

50 mg Film-Coated Tablet

Antidepressant

COMPOSITION:
Each film-coated tablet contains:
Sertraline HCl equivalent to Sertraline 50 mg.

PHARMACOLOGY:
Sertraline is a potent and specific inhibitor of serotonin (5-HT) uptake in vitro. At clinical doses, sertraline blocks the uptake of serotonin into human platelets.

PHARMACOKINETICS:
Sertraline is slowly absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 4.5 to 8.4 hours after ingestion. It undergoes extensive first-pass metabolism in the liver. The main pathway is demethylation to inactive N-desmethylsertraline, a process that appears to involve multiple cytochrome P450 isoenzymes; further metabolism and glucuronide conjugation occurs. Sertraline is widely distributed throughout body tissues and is about 98% bound to plasma proteins. The plasma elimination half-life of sertraline is reported to be about 26 hours; steady-state concentrations are achieved after about one week with regular oral doses. Sertraline is excreted in about equal amounts in the urine and feces, mainly as metabolites. Sertraline is distributed into breast milk.

INDICATIONS:
For the treatment of depression, obsessive compulsive disorder, panic disorder, social anxiety disorder, post-traumatic stress disorder, and treatment of premenstrual dysphoric disorder.

DOSAGE AND ADMINISTRATION:
Sertraline should be administered once daily, either in the morning or evening. Sertraline tablets can be administered with or without food. The therapeutic dose is 50 mg/day. This dose may be increased in case of lack of response to a maximum of 200 mg/day over a period of weeks.

CONTRAINDICATION:
Hypersensitivity to Sertraline.

PRECAUTIONS AND WARNINGS:
- Dosage during prolonged maintenance therapy should be kept at the lowest effective level, with subsequent adjustment depending on therapeutic response.
- The safety and effectiveness of sertraline in children have not been established.
- MAOI: cases of serious reactions have been reported in patients receiving sertraline in combination with monoamine oxidase inhibitors (MAOI). Symptoms of drug interaction between sertraline and a MAOI include: hyperthermia, rigidity, myoclonic, autonomic instability with possible rapid fluctuations of vital signs, mental status changes that include confusion, irritability and extreme agitation progressing to delinum and coma. These reactions have also been reported in patients who have recently discontinued sertraline and have been started on a MAOI. Some cases presented resemble neuroleptic malignant syndrome. Therefore, sertraline should not be used in combination with a MAOI, or within 14 days of discontinuing treatment with a MAOI. Similarly, at least 14 days should be allowed after stopping sertraline before starting a MAOI.
- Activation of mania/hypomania: During pre-marketing testing, hypomania or mania occurred in approximately 0.4% of sertraline-treated patients.
- Weight loss: Significant weight loss may be an undesirable result of treatment with sertraline for some patients. But on average, patients in controlled trials had minimal 1 - 2 pound weight loss versus smaller changes on placebo.
- Seizure: Seizures are potential risk with antidepressant and anti-obsessional drugs. The drugs should be discontinued in any patient who develops seizures.
- Suicide: The possibility of a suicide attempt is inherent in major depressive disorder and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy.

SPECIAL PRECAUTIONS:
Patients with hepatic insufficiency, electroconvulsive therapy and unstable epilepsy. It may impair ability to drive or operate machinery.

PREGNANCY AND LACTATION:
Sertraline should be used with caution in patients with hepatic or renal impairment; reduced doses should be considered in patients with hepatic impairment.

DRUG INTERACTIONS:
Monoamine oxidase inhibitors, alcohol, diazepam, tolbutamide, cimetidine, warfarin.

ADVERSE DRUG REACTIONS:
Frequently: Nausea, diarrhea, dyspepsia, tremor, dizziness, insomnia, increased sweating, dry mouth and male sexual dysfunction.
Infrequent: Hypertension, hypotension, tachycardia, ataxia, abnormal coordination, hyperesthesia, migraine, dysphagia, emotional lability, dysmenorrhea, bronchospasm and edema.

OVERDOSE AND TREATMENT:
Signs and Symptoms
Symptoms of overdose include serotonin-mediated side effects such as electrocardiogram QT

Paper of HVS 60 gsm, 113 mm x 245 mm, one column (in one side), two sides, one language (English language)

113 mm

245 mm

prolonged, TdP, somnolence, gastrointestinal disturbances (such as nausea, diarrhoea and vomiting), tachycardia, tremor, agitation and dizziness. Other important adverse events reported with sertraline overdose (single or multiple drugs) include bradycardia, bundle branch block, coma, convulsions, delirium, hallucinations, hypertension, hypotension, manic reaction, pancreatitis, QT-interval prolongation, stupor and syncope. Hyperthermia, increased respirations and cutaneous vasodilation have also been reported. Minor ECG abnormalities, palpitations, prolonged tachycardia and increased pulse rate have also been reported following paediatric overdose. Seizures have been reported rarely. Serotonin syndrome may result following significant overdose, and onset may be delayed. A death due to asthma exacerbation has been reported following sertraline overdose.
Deaths have been reported involving overdoses of sertraline, primarily in combination with other drugs and/or alcohol. Therefore any overdosage should be treated aggressively.
Elevated liver enzymes and elevated creatine phosphokinase levels have been noted following acute overdose. Hyponatraemia secondary to SIADH has been reported following overdose and has been severe enough to cause seizures.

Treatment of Overdosage

In managing overdosage, consider the possibility of multiple drug involvement. Treatment should consist of those general measures employed in the management of overdosage with any antidepressant. Cardiac and vital signs monitoring is recommended along with general symptomatic and supportive measures. Establish and maintain an airway, ensure adequate oxygenation and ventilation, if necessary. Patients should be monitored for potential cardiovascular, gastrointestinal, or hepatic abnormalities. Also monitor for signs/symptoms of serotonin syndrome (mental status changes, hyperthermia, myoclonus, autonomic instability, high CK levels) and possible seizures.
There are no specific antidotes for sertraline. Activated charcoal should be considered in treating overdose and is most effective when administered within one hour of ingestion. In patients who are not fully conscious or have impaired gag reflex, consideration should be given to administering activated charcoal via nasogastric tube once the airway is protected. Routine use of a cathartic with activated charcoal is not recommended as there is no evidence that cathartics reduce drug absorption and cathartics are known to cause adverse effects such as nausea, vomiting, abdominal cramps, electrolyte imbalances and occasionally hypotension.
Induction of emesis is not recommended because of the potential for CNS depression and seizures. Due to the large volume of distribution of sertraline, forced diuresis, dialysis, haemoperfusion, and exchange transfusion are unlikely to be of benefit.
In managing overdosage, consider the possibility of multiple drug involvement. The physician should consider contacting a poison control center on the treatment of any overdose.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

PACKAGING AVAILABLE (PACK SIZE):
ALU/PVC/PVDC blister pack of 10's.
(Box of 30`s)

CAUTIONS:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

REGISTRATION NUMBER:
DR-XY37372

DATE OF FIRST AUTHORIZATION:
21 January 2010

DATE OF REVISON OF PACKAGE INSERT:
January 2017

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER :

PROSWEAL
Healthcare Inc.

PROSWEAL HEALTHCARE, INC.
Unit 611 Common Goal Tower,
Finance cor Industry Sts.,
Madrigal Business Park, Ayala Alabang,
Muntinlupa City, Philippines.

NAME AND ADDRESS OF MANUFACTURER :

NOVELL
PHARMACEUTICAL
LABORATORIES

PT. NOVELL PHARMACEUTICAL LABORATORIES
Jl. Wanaherang No. 35, Tlajung Udik,
Gunung Putri, Bogor 16962, Indonesia

LFT/02/612