PRODUCT NAME	:	Serenata	**COUNTRY :** Philippines	**LOCATION :** Chhatral	**Supersedes A/W No.:**					
ITEM / PACK	:	Insert	**NO. OF COLORS:** 1	**REMARK :**						
DESIGN STYLE	:	-	**PANTONE SHADE NOS.:**	**SUBSTRATE :**						
CODE	:	XXXXXXXX-5343	Black	**Activities**	**Department**	**Name**	**Signature**	**Date**		
DIMENSIONS (MM)	:	150 x 240		Prepared By	**Pkg.Dev**					
ART WORK SIZE	:	S/S		Reviewed By	**Pkg.Dev**					
DATE	:	22-06-2017		Approved By	**Quality**					

XXXXXX-5343

SERTRALINE

SERENATA
50 mg Film-Coated Tablet
ANTIDEPRESSANT

Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders and those considering use of these agents must balance this risk with the clinical need.

FORMULATION:
Each film-coated tablet contains:
Sertraline ..... 50 mg
(As Sertraline Hydrochloride)

PRODUCT DESCRIPTION:
Sertraline (Serenata) 50 mg is a white to off white capsule shaped, biconvex, film coated tablet, with bisecting line on one side.

PHARMACODYNAMICS
Sertraline potently and selectively inhibits serotonin reuptake, thereby increasing the serotonin concentrations in synaptic cleft and prolongs its activity at postsynaptic receptor sites, which is reported to be responsible for its antidepressant action. It has only very weak effects on norepinephrine and dopamine neuronal reuptake. At clinical doses, sertraline blocks the uptake of serotonin into human platelets.
Like most clinically effective antidepressants, sertraline down regulates brain norepinephrine and serotonin receptors in animals. In receptor binding studies, sertraline has no significant affinity for adrenergic (alpha(1), alpha(2) and beta), cholinergic, GABA, dopaminergic, histaminergic, serotonergic (5-HT1A, 5-HT1B, 5- HT2) or benzodiazepine binding sites.

PHARMACOKINETICS
Sertraline is slowly absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 4.5 to 8.5 hours after ingestion. It undergoes extensive first-pass metabolism in the liver. The main pathway is demethylation to N-desmethylsertraline; further metabolism and glucuronide conjugation occurs. Sertraline is widely distributed throughout the body tissues and is highly (about 98%) bound to plasma proteins. The plasma elimination half-life of sertraline is reported to be 24 to 26 hours.
Sertraline is excreted in approximately equal amounts in the urine and faeces, mainly as metabolites. Sertraline is distributed into breast milk

INDICATIONS:
Used to treat depression and any connected feeling of anxiety, obsessive compulsive disorder and for females with post traumatic stress disorder

DOSAGE AND ADMINISTRATION:
Adults:
For the treatment and prevention of recurrence depression, an initial dosage of 50 mg once daily increased if necessary, in increments of 50 mg at intervals of at least a week to a maximum of 200 mg daily.

CONTRAINDICATION:
Contraindicated in patients with known hypersensitivity to sertraline.

WARNING AND PRECAUTIONS:
Sertraline should be used with caution and in reduced doses in patients with renal impaired hepatic or renal function and some authorities recommend that they should not be used in severe hepatic or renal failure.
In patients taking electroconvulsive therapy, Sertraline administration should be avoided.
Concomitant use of Sertraline and MAO Inhibitors should be avoided; at least 14 days should be elapsed between discontinuation of MAOs and initiation of Sertraline.
Since antidepressants may impair the ability to perform potentially hazardous tasks (driving a vehicle or operating machinery) the patient should be warned accordingly. Sertraline should be avoided in patients with unstable epilepsy. In case of controlled epilepsy patients should be carefully monitored and Sertraline should be discontinued if patients develops seizures.

PREGNANCY AND LACTATION:
Pregnancy
There are no adequate and well-controlled studies of Sertraline HCl in pregnant women; therefore, it should be used during pregnancy if clearly needed.
Nursing Mothers
It is not known whether, and if so in what amount, Sertraline or its metabolites are excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when Sertraline is given to lactating mother.

DRUG INTERACTIONS
The concomitant use of Sertraline and alcohol is not recommended. Caution is advised if Sertraline is administered with other centrally acting medications.
Sertraline, if given along with lithium and tryptophan may cause higher incidence of 5-HT associated adverse effects.
Because Sertraline is tightly bound to plasma proteins, the administration of Sertraline to a patient taking another drug which is highly bound proteins may cause a shift of plasma concentrations potentially resulting in an adverse effect. Conversely, adverse effects may result from displacement of protein bound Sertraline by another bound drug.

ADVERSE EFFECTS:
Some adverse effects reported with Sertraline include dry mouth, gastro-intestinal disturbances such as nausea, vomiting, dyspepsia, constipation and diarrhea. Anorexia and weight loss may also occur. Neurological adverse effects have included either anxiety, restlessness, nervousness and insomnia, or drowsiness and fatigue; headache, tremor, dizziness, convulsions, extrapyramidal effects and sexual dysfunction.
"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph or to TORRENT: www.torrentpharma.com".
Patient to seek medical attention immediately at the first sign of any adverse drug reaction shall appear.

OVERDOSAGE AND TREATMENT:
Important adverse events reported with sertraline hydrochloride overdose (single or multiple drugs) include bradycardia, bundle branch block, coma, convulsions, delirium, hallucinations, hypertension, hypotension, manic reaction, pancreatitis, QT-interval prolongation, serotonin syndrome, stupor, syncope and Torsade de Pointes.
Ensure an adequate airway, oxygenation and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with appropriate airway protection, if needed, may be indicated if performed soon after ingestion, or in symptomatic patients.
Activated charcoal should be administered. Due to large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion and exchange transfusion are unlikely to be of benefit. No specific antidotes for sertraline are known.

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

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

KEEP OUT OF REACH AND SIGHT OF CHILDREN

AVAILABILITY:
Sertraline (Serenata) 50 mg Film-Coated Tablet - Blister Pack of 10's (Box of 30's) - DRP - 2698

DATE OF FIRST AUTHORIZATION:
July 26, 2005

DATE OF REVISION:
August 2016

torrent PHARMA

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

Imported and Distributed by :
TORRENT PHARMA PHILIPPINES INC.
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