

xxxxxxx-5343

# SERTRALINE

**SERENATA  
50 mg 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)

**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.

**INDICATION**

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

**DOSAGE & 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 MAOIs 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.

**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 to proteins may cause a shift in 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.

**CAUTION**

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

**STORAGE CONDITION**

Store at temperatures not exceeding 30°C.

**AVAILABILITY**


In a box of 30's (Alu/PVC/PVDC blister pack of 10 tablets).

**KEEP OUT OF REACH AND SIGHT OF CHILDREN**



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

Imported and Distributed by :  
**TORRENT PHARMA PHILIPPINES INC.**  
Unit 601 6/F, ITC Building, 337 Sen.Gil Puyat Avenue,  
Makati City, PHILIPPINES

<b>PRODUCT NAME</b>	: Serenata	<b>COUNTRY</b>	: Philippines	<b>LOCATION</b>	: Chhatral	<b>Supersedes A/W No.:</b>		
<b>ITEM / PACK</b>	: Insert	<b>NO. OF COLORS:</b>	1	<b>REMARK :</b>				
<b>DESIGN STYLE</b>	: -	<b>PANTONE SHADE NOS.:</b>		<b>SUBSTRATE :</b>				
<b>CODE</b>	: xxxxxxxx-5343			<b>Activities</b>	<b>Department</b>	<b>Name</b>	<b>Signature</b>	<b>Date</b>
<b>DIMENSIONS (MM)</b>	: 150 x 180			Prepared By	Pkg.Dev			
<b>ART WORK SIZE</b>	: S/S			Reviewed By	Pkg.Dev			
<b>DATE</b>	: 03-06-2015		Black	Reviewed By	RA			
				Approved By	CQA			