**SERTINE®**
**50 mg Tablets**

**Dear patient,**
**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

**Information about SERTINE**
Each SERTINE tablet for oral administration contains sertraline hydrochloride equivalent to 50 mg sertraline with the following excipients: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, magnesium stearate, talc, yellow quinoleine.
Sertraline is a selective serotonin reuptake inhibitor (SSRI).
SERTINE is indicated in the following conditions:
- Treatment of major depressive disorder in adults
- Treatment of obsessions and compulsions in adults and pediatric patients with obsessive-compulsive disorder
- Treatment of panic disorder in adults, with or without agoraphobia
- Treatment of posttraumatic stress disorder in adults
- Treatment of social anxiety disorder (also known as social phobia) in adults
- Treatment of premenstrual dysphoric disorder in adults: SERTINE produces beneficial effects in controlling both the psychological and somatic symptoms of women with premenstrual syndrome

SERTINE may be used to treat other conditions as well such as treatment of premature ejaculation**.**

**The way to take SERTINE**
Take SERTINE as directed by your physician. Do not discontinue the treatment without consulting your doctor.
Dosage and duration of treatment are individualized and adjusted according to the condition under treatment and the response obtained.
SERTINE is given as a single dose in the morning or evening, with meals.
The usual recommended doses are:

| **Indication** | **Adult dose** |
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| Major depressive Disorder | The usual initial dose is 50 mg (1 tablet) once daily |
| Obsessive-Compulsive disorder | The usual initial dose is 50 mg (1 tablet) once daily |
| Panic disorder | The usual initial dose is 25 mg once daily (half a tablet of 50 mg once daily) increased after one week to 50 mg once daily (1 tablet once daily) |
| Posttraumatic stress disorder | The usual initial dose is 25 mg once daily (half a tablet of 50 mg once daily) increased after one week to 50 mg once daily (1 tablet once daily) |
| Social anxiety disorder | The usual initial dose is 25 mg once daily (half a tablet of 50 mg once daily) increased after one week to 50 mg once daily (1 tablet once daily) |
| Premenstrual dysphoric disorder | Two dosing schedules may be recommended depending on physician assessment:<br>- Daily administration throughout the menstrual cycle:<br>Treatment may be initiated with a dose of 50 mg (1 tablet) per day given daily throughout the menstrual cycle.<br>Patients not responding to a 50 mg/day dose may benefit from dose increase by 50 mg at the onset of each menstrual cycle up to a maximum of 150 mg daily<br>- Daily administration limited to the luteal phase of the menstrual |

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| | cycle<br>Treatment may be initiated with a dose of 50 mg (1 tablet) per day given daily throughout the luteal phase of the menstrual cycle.<br>Patients not responding to a 50 mg/day dose may benefit from dose increase (at 50 mg increments/menstrual cycle) up to 100 mg/day.<br>Patients who require 100 mg daily during luteal phase-only dosing should initially be given 50 mg daily for the first 3 days of each luteal phase dosing period |

The initial dose in *major depressive disorder, obsessive-compulsive disorder, panic disorder, posttraumatic stress disorder or social anxiety disorder* may be increased, if necessary, in increments of 50 mg at intervals of at least a week to a maximum of 200 mg daily.
For the *treatment of premature ejaculation*, SERTINE is generally administered in daily dosages ranging from about 50-200 mg per day, although variations will necessarily occur depending upon the condition of the subject being treated; in certain conditions, doses of 50 mg can be given at 5 p.m. (4 to 8 hours before intercourse).
Otherwise patient may be started on 50 mg daily for 2 weeks, and the dose is then adjusted to 50 or 100 mg on the day of intercourse only.
*Dosage for pediatric population (children and adolescents) in the treatment of obsessive-compulsive disorder:*
- In children aged 6 to 12 years the usual initial dose is 25 mg (half a tablet of 50 mg) once daily. Patients not responding to the initial dose may benefit from dose increases in increments of 25 mg at intervals of at least a week to a maximum of 200 mg daily.
- Adolescents (13 to 17 years) may be started on 50 mg (1 tablet) once daily. Patients not responding to the initial dose may benefit from dose increases up 200 mg/day.

**Duration of treatment**
Duration of treatment is determined according to the disease under treatment.
Acute episodes of psychiatric disorders require several months or longer of sustained therapy beyond response to initial treatment.
Patients should be periodically reassessed to determine the need for maintenance treatment.

**In case of overdose**
In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

**In case of missed dose**
If you miss a dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

**Contraindications**
This drug is contraindicated in case of:
- History of hypersensitivity to any of the components
- Concomitant use with monoamine oxidase inhibitors (MAOIs)
- Concomitant use with pimozide

**Precautions**
- Antidepressants are associated with an increased risk of potentially suicidal thinking and behavior when used for the treatment of psychiatric disorders in children and adolescents. All pediatric patients being treated with antidepressants should be observed closely for unusual changes in behavior.
- 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 until significant improvement in depression is observed.
- Reduced doses are recommended in patients with hepatic impairment.
- This drug should be used with care in patients with a seizure disorder or liver disease.

- Do not stop taking this medicine without first checking with your doctor. He may want you to reduce gradually the amount you are taking before stopping completely. Antidepressants should be withdrawn gradually to reduce the risk of withdrawal symptoms.
- The doctor should be informed in case of emergence of anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness or other unusual changes in the patient's behavior.
- Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.
- Consult your doctor before using this medication in case of pregnancy or lactation. This drug should be used during pregnancy only if clearly needed. Caution should be used when it is administered to a nursing woman.

**Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.
This drug should not be used in combination with a MAOI, or within 14 days of discontinuing treatment with a MAOI.
The concomitant use of this drug and alcohol is not recommended.
Caution should be used when administered concomitantly with NSAIDs, aspirin, oral anticoagulants or other drugs that affect coagulation.
Use with caution with cimetidine, sumatriptan, methadone, diazepam, lithium, tricyclic antidepressants, and other central nervous system active drugs.

**Adverse reactions**

The most reported adverse reactions include headache, insomnia, anorexia, nausea, agitation, tremor, diarrhea, dyspepsia, dry mouth, dizziness, fatigue, and somnolence.
Rarely reported adverse reactions include hyponatremia, weight loss, tachycardia, ejaculation delay, constipation, increased sweating, rash, pruritus, activation of mania, increase in liver enzymes and convulsions.
Inform your doctor if any side effect appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.
The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

SERTINE, sertraline 50 mg, pack of 15 tablets
SERTINE, sertraline 50 mg, pack of 30 tablets

**Revision date: 06/2011**
SERT5/003