OLOFT
(Sertraline)

50mg
&
100mg
Tablets

اولوفٹ
(سرٹرالین)

COMPOSITION:
Each film coated tablet contains:
Sertraline HCl eq. to Sertraline.....50mg
Product Complies Nexus specifications.

Each film coated tablet contains:
Sertraline HCl eq. to Sertraline.....100mg
Product Complies Nexus specifications.

MECHANISM OF ACTION:
Sertraline is a potent and specific inhibitor of neuronal Serotonin (5HT) uptake in vitro which results in the potentiation of the effects of 5HT. It has only 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 accord with its selective inhibition of 5HT uptake, sertraline does not enhance catecholaminergic activity. Sertraline has no significant affinity for muscurinic (cholinergic) serotonirgic, dopaminergic, adrenergic, histaminergic, GABA or benzodiazipine receptors.

PHARMACOKINETICS:
In man, following oral once daily dosing over the range of 50 to 200 mg for 14 days, peak plasma concentrations (Cmax) of sertraline occurred between 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 approximately 26 hours for young and elderly men and women. 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 is excreted in the urine. Food does not significantly change the bioavailability of sertraline tablets.

INDICATIONS:
OLOFT is used or the following indications:
- Major Depressive Disorder (MDD)
- Obsessive Compulsive Disorder (OCD)
- Panic Disorder
- Post-traumatic Stress Disorder (PTSD)
- Social Anxiety Disorder
- Premenstrual Dysphoric Disorder (PMDD)

CONTRA-INDICATIONS:
Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated.
Concomitant use in patients taking Pimozide is contraindicated.
OLOFT is contraindicated in patients with hypersensitivity to Sertraline or any of the inactive ingredients in OLOFT

DOSAGE AND ADMINISTRATION
Major Depressive Disorder
OLOFT Treatment should be administered at a dose of 50 mg once daily.
Obsessive Compulsive Disorder
OLOFT Treatment should be administered at a dose of 50 mg once daily.
Panic Disorder, Post-traumatic Stress Disorder and Social Anxiety Disorder - OLOFT treatment should be initiated with a dose of 25mg once daily. After one week, the dose should be increased to 50mg once daily.
Premenstrual Dysphoric Disorder - OLOFT treatment should be initiated with a dose of 50 mg/day, either daily throughout the menstrual cycle or limited to the luteal phase of the menstrual cycle, depending on physician assessment.

OLOFT should be administered once daily, either in the morning or evening.

Use in Children:
The safety and effectiveness of sertraline in children have not been fully established.

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

ADVERSE EFFECTS:
Side effects which occurred significantly more frequently with sertraline are nausea, diarrhoea/loose stools, anorexia, dyspepsia, tremor, dizziness, insomnia, somnolence, increased sweating, dry mouth, and sexual dysfunction (primarily ejaculatory delay in males).

PRECAUTIONS:
Monoamine Oxidase Inhibitors - Cases of serious reactions, some times fatal have been reported in patients receiving sertraline in combination with a monoamine oxidase inhibitor (MAOIs), including the selective MAOI, sertraline should not be used in combination with MAOI or within 14 days of discontinuing treatment with MAOI. Similarly, atleast 14 days should elapse after discontinuing sertraline treatment before starting MAOI.

Other Serotonergic drugs:
Co-administration of sertraline 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 are a potential risk with antidepressant and antiobsessional drugs. It should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. The drug should be discontinued in any patient who develops seizures.

Use in Hepatic Insufficiency:
The use of sertraline in patients with hepatic disease must be approached with caution. If Sertraline is administered to patients with hepatic impairment, a lower or less frequent dose should be considered.

Use in Renal Insufficiency:
Since sertraline is extensively metabolized, excretion of unchanged drug in urine is a minor route of elimination. Sertraline dosing does not have to be adjusted based on the degree of renal impairment.

Pregnancy and Lactation:

Use in Pregnancy:
Reproduction studies have been performed in rats and rabbits in doses upto approximately 20 times and 10 times the maximum daily human mg/kg dose, respectively. There was no evidence of teratogenicity at any dose level. There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, sertraline should be used during pregnancy only if the perceived benefits outweigh the risks.

Women of childbearing potential should employ an adequate method of contraception if taking sertraline.

Use During Lactation:
Use in nursing mothers is not recommended unless in the judgment of the physician, the benefit out weight the risk.

DRUG INTERACTION:

CNS Depressants & Alcohol:
The co-administration of sertraline 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 is bound to plasma proteins, the potential of sertraline 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. Co-administration of sertraline 200 mg daily with diazepam of tolbutamide resulted in `small statistically significant changes in some pharmacokinetic parameters. Co-administration with cimetidine caused a substantial decrease in sertraline clearance. The clinical significance of these changes is unknown. Sertraline has not effect on the beta-adrenergic blocking ability of atenolol. No interaction of sertraline 200 mg daily was observed with glibenclamide or digoxin.

Warfarin:
Co-administration of sertraline 200 mg daily with warfarin resulted in small but statistically significant increase in prothrombin time, the clinical significance of which is unknown. Accordingly prothrombin time should be carefully monitored when sertraline therapy is initiated or stopped.

OVERDOSE:
Sertraline has a wide margin of safety in overdose. Overdoses of sertraline alone of upto 6g have been reported. However any overdosage should be treated aggressively.

No specific therapy is recommended and there are no specific antidotes to sertraline. Establish and maintain an airway, insure adequate oxygenation and ventilation. Activated charcoal, which may be used with a cathartic, may be as or more effective than emesis or lavage and should be considered in treating overdose. Cardiac and vital signs monitoring is recommended along with general symptomatic and supportive measures. Due to the large volume of distribution of sertraline, forced diuresis, dialysis, hemoperfu sion and exchange transfusion are unlikely to be of benefit.

STORAGE
Store below 30°C in a dry place, protect from light.
Keep out of the reach of children.
Dosage as directed by the physician.
To be sold on the prescription of a registered medical practitioner only.

PRESENTATIONS
OLOFT 50 mg tablets are available in the blister pack of 30's
OLOFT 100mg tablets are available in the blister pack of 20's

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

Manufactured by:
NEXUS
Nexus Pharma (Pvt.) Ltd.
Plot NO. 4/19 - 4/36, Sector 21,
Korangi Industrial Area, Karachi.

Marketed by:
ORGANIC Pharmaceuticals