120mm

180mm

Depralin-50 Tablet
Depralin-100
(SertralineHCl)

ڈپرالین-۵۰ ٹیبلیٹ
ڈپرالین-۱۰۰
(سرٹرالین ہائیڈروکلورائیڈ)

COMPOSITION:
Depralin-50 Tablet
Each film coated tablet contains:
Sertraline (as HCl).....50mg
(USP Specification)
Depralin-100 Tablet
Each film coated tablet contains:
Sertraline (as HCl).....100mg
(USP Specification)

DRUG DESCRIPTION:
Depralin (sertraline hydrochloride) is a selective serotonin reuptake inhibitor (SSRI) for oral administration. Sertraline hydrochloride is a white crystalline powder that is slightly soluble in water and isopropyl alcohol, and sparingly soluble in ethanol.

CLINICAL PHARMACOLOGY:
MECHANISM OF ACTION
The mechanism of action of sertraline is presumed to be linked to its inhibition of CNS neuronal uptake of serotonin (5HT). Studies at clinically relevant doses in man have demonstrated that sertraline blocks the uptake of serotonin into human platelets. In vitro studies in animals also suggest that sertraline is a potent and selective inhibitor of neuronal serotonin reuptake and has only very weak effects on norepinephrine and dopamine neuronal reuptake.

PHARMACOKINETICS:
In man, following oral once-daily dosing over the range of 50 to 200mg for 14 days, mean peak plasma concentrations (Cmax) of sertraline occurred between 4.5 to 8.4 hours post-dosing. The average terminal elimination half-life of plasma sertraline is about 26 hours. Based on this pharmacokinetic parameter, steady-state sertraline plasma levels should be achieved after approximately one week of once-daily dosing. Linear dose-proportional pharmacokinetics were demonstrated in a single dose study in which the Cmax and area under the plasma concentration time curve (AUC) of sertraline were proportional to dose over a range of 50 to 200 mg. Consistent with the terminal elimination half-life, there is an approximately two-fold accumulation, compared to a single dose, of sertraline with repeated dosing over a 50 to 200 mg dose range. The single dose bioavailability of sertraline tablets is approximately equal to an equivalent dose of solution.

INDICATIONS:
Major Depressive Disorder
Depralin (sertraline hydrochloride) is indicated for the treatment of major depressive disorder in adults. The efficacy of Depralin in the treatment of a major depressive episode was established in six to eight week controlled trials of adult out patients whose diagnoses corresponde most closely to the DSM-IIII category of major depressive. A major depressive episode implies a prominent and relatively persistent depressed or dysphoric mood that usually interferes with daily functioning (nearly every day for at least 2 weeks); it should include at least 4 of the following 8 symptoms: change in appetite, change in sleep, psychomotor agitation or retardation, loss of interest in usual activities or decrease in sexual drive, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, and a suicide attempt or suicidal ideation.

DOSAGE AND ADMINISTRATION:
Major Depressive Disorder and Obsessive - Compulsive Disorder: Depralin treatment should be administered at a dose of 50 mg once daily.
Panic Disorder, Post traumatic Stress Disorder and Social Anxiety Disorder - Depralin treatment should be initiated with a dose of 25 mg once daily. After one week, the dose should be increased to 50 mg once daily. While a realtionship between dose and effect has not been established for major depressive disorder, OCD, panic disorder, PTSD or social anxiety disorder, patients were dosed in a range of 50-200 mg/day in the clinical trials demonstrating the effectiveness of Depralin for the treatment of these indications. Consequently, a dose of 50 mg, administered once daily, is recommended as the initial therapeutic dose. Patients not responding to a 50 mg dose may benefit from dose increases up to a maximum of 200 mg/day. Given the 24 hour elimination half-life of Depralin, dose changes should not occur at intervals of less than 1 week.

SIDE EFFECTS:
During its premarketing assessment, multiple doses of Depralin were administered to over 4000 adult subjects as of February 18, 2000. The conditions and duration of exposure to Depralin varied greatly, and included (in overlapping categories) clinical pharmacology studies, open and double-blind studies, uncontrolled and controlled studies, inpatient and outpatient studies, fixed-dose and titration studies, and studies for multiple indications, including major depressive disorder, OCD, panic disorder, PTSD, PMDD and social anxiety disorder.

PRECAUTIONS:
Discontinuation of Treatment with Depralin
During marketing of Depralin and other SSRIs and SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g. paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self- limiting, there have been reports of serious discontinuation symptoms.

CONTRAINDICATIONS:
All Dosage Forms of Depralin
Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated. Concomitant use in patients taking pimozide is contraindicated.
Depralin is contraindicated in patients with a hypersensitivity to sertraline or any of the inactive ingredients in Depralin.

STORAGE & INSTRUCTIONS:
Store between 15-25°C.
Protect from heat, sunlight & moisture. Keep away from the reach of children.
To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:
Depralin-50 Tablet:
30's Tablets
Depralin-100 Tablet:
20's Tablets

خوراک وطریقہ استعمال:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:
دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549 Sundar Industrial Estate, Lahore, Pakistan.