

Moodapex F.C. Tablets

Sertraline

Antidepressant.

COMPOSITION:

Moodapex: 50 mg sertraline.

PROPERTIES:

The antidepressant effect of sertraline is due to its ability to inhibit the neuronal reuptake of serotonin. It has very weak effects on norepinephrine and dopamine neuronal reuptake. Like most clinically effective antidepressants, sertraline downregulates brain norepinephrine in animals. In receptor binding studies, sertraline has no significant affinity for adrenergic (alpha 1, alpha 2 & beta), GABA, dopaminergic, cholinergic, histaminergic, serotonergic (5-HT1A, 5-HT1B, 5-HT2), or benzodiazepine binding sites. The maximum concentration of sertraline in the plasma occurs after 4.50-8.40 hours of oral administration. The average terminal elimination life is approximately 26 hours.

Food increases the bioavailability by about 40%.

Plasma protein binding is about 98%.

INDICATIONS:

- For the symptomatic relief of depressive illness including depression accompanied by symptoms of anxiety.
- Preventing relapse of the initial episodes of depression or recurrent episodes.
- Treatment of obsessive compulsive disorders.

DOSAGE AND ADMINISTRATION:

50 mg/day either in the morning or in the evening and could be increased gradually to 200 mg/day within one week.

Daily dose of 150 mg or more should not be given for longer than 8 weeks after that the maintenance dose could be reduced to 50 mg/day.

CONTRAINDICATIONS:

Patients with known hypersensitivity to sertraline.

PRECAUTIONS AND WARNINGS:

- Sertraline should not be used with MAO inhibitors since this combination may induce hyperthermia, rigidity and mental status changes.
- Activation of mania or hypomania occurred in 0.6% of sertraline treated patients.
- Like any psycho-active drug, sertraline may impair judgment, thinking or motor skills.
- In renal or hepatic dysfunction, sertraline should be used with care.
- In pregnancy and lactation, the product should not be used unless the potential benefits justify the possible risk.
- **Seizure Disorders:** In previous suicidal attempts, the drug should be prescribed at the least effective dose.
- Myocardial infarction or unstable heart disease.

DRUG INTERACTIONS:

- Cimetidine inhibits the metabolism of sertraline and may result in decrease in the clearance and first pass metabolism with a possible increase in drug related side effects.
- Alcohol.
- Tricyclic antidepressants.
- Hypoglycemic drugs.
- Warfarin, digoxin and atenolol.

SIDE EFFECTS:

G.I.T. disorders e.g. nausea, vomiting, and diarrhea.

Male sexual dysfunction (ejaculatory delay), increased sweating, tremor, dry mouth dizziness, tinnitus, rhinitis, and weight loss. Hypertonia, hyperthermia, vertigo, ataxia, migraine, hyperkinesia arid myalgia. Menstrual disorders and dysmenorrhea. Skin rash, urticaria, dry skin and eczema.

The majority of the above side effects occur when dose reaches 200 mg/day.

PACKAGE AND STORAGE:

Moodapex 50 mg:

Pack of 10 film coated tablets.

Pack of 20 film coated tablets.

Pack of 30 film coated tablets.

Store in a dry place at temperature not exceeding 30° C.

Keep All Medicines Out of Reach of Children

Manufactured by: Apex Pharma - S.A.E - Badr City - Egypt.

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