

Modipran®

Capsule

Description

Modipran is a preparation of Fluoxetine Hydrochloride BP. Fluoxetine Hydrochloride is a selective inhibitor of serotonin reuptake in presynaptic neurons and is used as an antidepressant with very long half life.

Indications

Modipran (Fluoxetine Hydrochloride) is indicated for the treatment of depressive illness, bulimia nervosa and obsessive compulsive disorder.

Dosage and Administration

Initial treatment :

Recent studies suggest that 20 mg/day of Fluoxetine may be sufficient to obtain satisfactory antidepressant response. Consequently, a dose of 20 mg/day administered in the morning is recommended as the initial dose.

A dose increase may be considered after several weeks if no clinical improvement is observed. Dosage above 20 mg/day, should be administered on a bid schedule (i.e. morning and noon) and should not exceed a maximum dose of 80 mg/day. As with other antidepressants, the full antidepressant effect may be delayed until 4 weeks of treatment or longer. As with many other medications, a lower or less frequent dosage should be used in patients with renal and/or hepatic impairment.

A lower or less frequent dosage should also be considered for patients, such as elderly, with concurrent disease or on multiple medication. A recommended maximum dose for elderly patients is 60 mg per day.

Maintenance treatment :

It is generally agreed among expert psychopharmacologists that acute episode of depression requires several months or longer sustained pharmacologic therapy. Fluoxetine is also used in dosage of 60 mg daily for the management of bulimia nervosa.

Contraindications

Modipran (Fluoxetine Hydrochloride) is contraindicated in patients known to be hypersensitive to it.

Monoamine oxidase inhibitors : There have been reports of serious, sometimes fatal reactions (including hyperthermia, rigidity, myoclonus, autonomic instability with possible rapid fluctuations of vital signs and changes of mental status that include extreme agitation progressing to delirium and coma) in patients receiving Fluoxetine in combination with monoamine oxidase inhibitors (MAOIs), and in patients who have recently discontinued Fluoxetine and are then started on MAOIs. Some cases presented with features resembling neuroleptic malignant syndrome. Therefore, Modipran should not be used in combination with MAOI, or within 14 days of discontinuing therapy with MAOI. Since Fluoxetine and its major metabolites have very long elimination half-lives, at least 5 weeks should be allowed after stopping Fluoxetine and before starting MAOI.

Precautions

As Fluoxetine undergoes hepatic metabolism and renal excretion, it should be used with caution and in reduced doses in patients with impaired hepatic or renal function. Because of its epileptogenic effect, it should be used with caution in patients with epilepsy or a history of such disorders. Fluoxetine may alter glycaemic control and therefore caution is also warranted in diabetic subjects.

Depressed patients with suicidal tendencies should be carefully supervised during treatment. Fluoxetine is not usually considered a suitable form of therapy for the depressive component of bipolar (manic depressive) illness as mania may be precipitated.

Use in children : Safety and effectiveness in children have not been established.

Side Effects

Gastrointestinal : Nausea, vomiting, dyspepsia, dry mouth, and diarrhoea.

Neurological : Anxiety, nervousness, insomnia/drowsiness and fatigue.

Others : Excessive sweating, pruritus, skin rashes associated with liver, kidney and lung involvement. It has therefore been advised that Fluoxetine therapy should be discontinued in any patient who develops a skin rash.

Use in Special Populations

Pregnancy : In animal studies, no teratogenicity or harmful effect was found. Because animal reproductive studies are not always predictive of human responses, Fluoxetine should be used in pregnancy only if clearly needed.

Lactation : As Fluoxetine is excreted in human milk, caution should be exercised when Fluoxetine is administered to nursing women.

Commercial Pack

Modipran® Capsule : Box containing 10 aluminium strips of 10 capsules. Each capsule contains Fluoxetine Hydrochloride BP equivalent to Fluoxetine 20 mg.