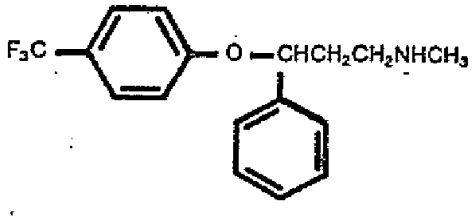
FLUXIL

Fluxil capsules 20 mg: 30's

Active Ingredient: Fluoxetine hydrochloride corresponding to 20mg fluoxetine



Indications:

Adult

Depression

Fluxil is indicated for the treatment of the symptoms of depressive illness, with or without associated anxiety symptoms, especially where sedation is not required.

Obsessive-compulsive disorder

Bulimia nervosa

Fluxil is indicated for the reduction of binge-eating and purging activity.

Administration & Dosage:

Depression, with or without associated anxiety symptoms

Adults and the elderly: A dose of 20 mg/day is recommended

Obsessive compulsive disorder

Adults and the elderly: 20 mg/day to 60 mg/day. A dose of 20mg/day is recommended as initial dose. Although there may be an increased potential for side effects at higher doses, a dose increase may be considered after several weeks if there is no response.

Bulimia Nervosa

Adults and the elderly: A dose of 60 mg/day is recommended.

All indications

The recommended dose may be increased or decreased. Doses above 80 mg/day have not been systematically evaluated.

Children

The use of fluoxetine in children is not recommended, as safety and efficacy have not been established.

Hepatic impairment

A lower or less frequent dose (e.g. 20mg every second day) should be considered in patients with hepatic impairment, or in patients where concomitant medication has the potential for interaction with fluoxetine.

Withdrawal symptoms seen on discontinuation of fluoxetine

Abrupt discontinuation should be avoided. When stopping treatment with Fluxil the dose should be gradually reduced over a period of at least one to two weeks in order to reduce the risk of withdrawal reactions. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose, but at a more gradual rate.

Method of administration

For oral administration, with or without food. When dosing is stopped, active drug substances will persist in the body for weeks. This should be borne in mind when starting or stopping treatment.

Contra-indications:

Hypersensitivity to fluoxetine

Patients taking monoamine oxidase inhibitor (MAOI) drugs

Warnings & Precautions:

Serious reactions may occur if given together with MAOIs or tricyclics. At least 14 days should pass between discontinuation of MAOI and initiation of treatment with fluoxetine. Because of the long half life of fluoxetine, at least 5 weeks should pass between discontinuation of fluoxetine and initiation with a MAOI.

The possibility of suicide attempt is inherent in depression, close supervision of high risk patients is advised.

As with any psychoactive drug, impaired judgement or motor skills may occur, and patients should not drive or operate machinery. Anaphylactoid events, including bronchospasm, and angioedema, and progressive systemic events, sometimes serious (involving skin, kidney, liver or lung) have been reported. Use cautiously in patients who have a history of seizures, mania/hypomania, cardiac disease. As fluoxetine is metabolized by the liver and excreted by the kidneys, a lower dosage or alternate day dosing is recommended for patients with renal or hepatic impairment. In patients with diabetes hypoglycaemia has occurred during treatment with fluoxetine and hyperglycermia has developed following discontinuation.

Sexual dysfunction

Selective serotonin reuptake inhibitors (SSRIs)/serotonin norepinephrine reuptake inhibitors (SNRIs) may cause symptoms of sexual dysfunction. There have been reports of long-lasting sexual dysfunction where the symptoms have continued despite discontinuation of SSRIs/SNRIs.

Pregnancy & Lactation:

Fluoxetine crosses the placenta and may produce effects in the newborn. It is not recommended during pregnancy and breast feeding.

Drug Interactions:

Fluoxetine, like other drugs metabolized by P450 inhibits the activity of this enzyme. Drugs that are metabolized by this enzyme (eg flecainide, encainide, vinblastine, ketoconazole, astemizole, cisapride, midazolam etc) should be avoided or used at the low end of the dose range if a patient is on fluoxetine concurrently or have been on it within the last 5 weeks. Altered anticoagulant effect, including increased bleeding, with warfarin has been reported and coagulation monitoring is necessary. Similarly, changes in blood levels of carbamazepine, haloperidol, clozapine,

diazepam, alprazolam, lithium, phenytoin, and cyclic antidepressants (eg imipramine, desipramine) have been observed. Co-administration with serotonergic drugs (tramadol, sumatriptan) may lead to increase of 5HT associated effects. Increased effects have been observed when a SSRI is given with lithium or tryptophan. There have been rare reports of prolonged seizures in patients on fluoxetine receiving, ECT treatment. Undesirable effects may also occur when patients on fluoxetine take alcohol or St. John's Wort (Hypericum Perforatum)

Adverse Reactions:

Nervous system: anxiety, nervousness, dizziness, drowsiness, insomnia, fatigue, headache, sleep abnormalities, euphoria, twitching, ataxia, tremor, seizures, psychomotor restlessness, hallucinations, mania, confusion, agitation, panic attacks, etc Gastrointestinal: anorexia, nausea, diarrhea, vomiting, dyspepsia, dysphagia, taste perversion.
Respiratory: yawn, epistaxis, hyperventilation, asthma
Skin: rash, puritus, urticaria, vasculitis, alopecia, angioedema, photosensitivity, bleeding abnormalities eg ecchymosis and purpura
Others: anaphylactoid reaction, serum sickness, chills, serotonin syndrome, dry mouth, weight loss

Pharmacology & Pharmacokinetics:

Fluoxetine is a selective inhibitor of serotonin reuptake (SSRI). It is well absorbed after oral administration. Peak concentration is reached in 6 to 8 hours and is widely distributed and extensively bound to plasma proteins. It is metabolized by cytochrome P450 isoenzymes in the liver to norfluoxetine and other metabolites and are excreted in urine. Elimination half life of fluoxetine is 4 to 6 days and that of its active metabolite is 4 to 16 days. The long elimination half lives should be taken into consideration when drugs are prescribed that might interact with fluoxetine (see precautions).

Overdosage:

Symptoms caused by overdosage are usually mild; usual symptoms are shaky hands, vomiting, nausea, seizures, cardiovascular and respiratory dysfunction, altered CNS status ranging from excitation to coma. Establish and maintain an

airway; ensure adequate oxygenation and ventilation. Activated charcoal together with sorbitol may be used to prevent further absorption of fluoxetine.

Storage:

Store below 25°C in a dry place

Keep out of reach of children

Delorbis Pharmaceuticals Ltd., 17 Athinon Street, Ergates Industrial Area, 2643 Ergates, P.O. Box 28629, 2081 Lefkosia, Cyprus.

Product Registration Holder: Zyfas Medical Co., 102E Pasir Panjang Road, #02-10/11 Citilink Warehouse Complex Singapore 118529