# OXEFLU

## (Fluoxetine HCl) Capsules, USP

آکسی فلو کیپسولز

**WARNING:**

**SUICIDALITY AND ANTIDEPRESSANT DRUGS**

Antidepressants increased the risk of suicidital thoughts and behavior in children adclescents and young adults in short term studies. These studies did not show and increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24 there was a reduction in risk with antidepressant use in patients aged 65 and older.

In patients of all ages who are started on antidepressant therapy monitor closely for worsening and for emergence of sudical thoughts and behaviors. Advise familles and caregivers of the need for close observation and communication with the prescribe.

Flucoxetine is not approved for use in children less than 7 years of age.

**COMPOSITION:**

Each capsules contains:

Fluoxetine as HCl ..... 20mg.

(USP Specs)

**DESCRIPTION:**

Fluoxetine capsule is a selective serotonin reuptake inhibitor for oral administration. It is also marketed for the treatment of premenstrual dysphoric disorder, its chemical name is (+)-N-methyl-3-phenyl-3-[4-(trifluromethyl) phenoxy] -1-propylamine hydrochloride, molecular formula is $C_{17}H_{18}F_3NO.HCl$ and molecular weight is 345.79

**INDICATIONS:**

Major Depressive Disorder: fluoxetine is indicated for the acute and maintenance treatment of major Depressive Disorder in adult patients and in pediatric patient aged 8 to 18 years. The usefulness of the drug in adult and pediatric patients receiving -fluoxetine for extentded periods should periodically be reevaluated.

**OBSESSIVE COMPULSIVE DISORDER:**

Fluoxetine is indicated for the acute and maintenance treatment of obsessions and compulsions in adult patients and in pediatric patients aged 7 to 17 years with obsessive compulsive disorder (OCD).

**BULIMIA NERVOSA:**

Fluxoetine is indicated for the acute and maintenance treatment of beinge-eating and vomiting behaviors in adults patiens with moderate to severe bulimia Nervose.

**PANIC DISORDER:**

Fluxetine is indicated for the acute treatment of panic disorder, with or without agoraphobia, in adult patients.

**DOSAGE AND ADMINISTRATION:**

**RECOMMENDED DOSAGE:**

| INDICATION | ADULT | .PEDIATIC |
|---|---|---|
| MDO | 20mg/day in am (initial dose) | 10 to 20mg/day (initial dose) |
| OCD | 20mg/day in am (initial dose) | 10mg/day (initial dose) |
| Bulimia Nervosa | 60mg/day (initial dose) | - |
| Panic Disorder | 10mg/da | - |
| Depressive Episodes Assocated with Bipolar I Disorder | Oral incornbination with olanzapine: 5mg of oral otanzapine and 20mg of fluoxetine once daily (initial dose) | Oral in combination iwth olanzapine: 2.5mg of oral olanzapine and 20mg of fluoxetine once daily (initial dose) |
| Treatment Resistant Depression | Oral in combination with olanzapine: 5mg of oral olanzapine and 20mg of fluoxetine once daily (initial dose) | |

**Pharmacology:**

**Mechanism of action:** Although the exact mechanism of fluoxetine is unknown, it is presumed to be linked to its inhibition of CNS neuronal uptake of serotonin.

**Pharmacodynamics:**

Studies at clinically relevant doses in man have demonstrated that fluoxetin blocks the uptake of serotonin into human platelets. Studies in animals also suggest that fluoxetine is a much more potent uptake inhibitor in serotonin than of norepinephrine.

Anatgonism of muscarinicm, histaminergicm and -1-adrenergic receptors has been hypothesized to be associated with various anticholinergic sedative and cardiovascular effects of classical tricyclic antidepressant (TCA) drugs. Fluoxetine binds to these and other memebrance receptors form brain tissue much less potently in vitro than do the tricyclic drugs.

**PHARMACOKINETICS:**

**SYSTEMIC BIOVAILABILITY:**

In man, following a single oral 40mg dose, peak plasma concentration of fluoxetine form 15 to 55mg/ml are observed after 6 to 8 hours.

**Metabolism:** Fluoxetine is extensively metabolized in the liver to norfluoxetine and a number of other unidentified metabolities. The only identified active metabolite, norfluoxetine, is formed by demethylation of fluoxetine.

**Accumulation and Slow Elimination:** The relatively slow elimination of fluoxetine (elimination half-life of 1 to 3 days after acute administration and 4 to 5 days after chronic administration) and its active metabolite, norfluoxetine (elimination half-life of 4 to 16 days after acute and chronic administration), leads to significant accumulation of these active species in chronic use and delayed altainment of steady state, even when a fixed dose is used.

**Interactions with Medicines:** As with all drugs like Monoamine Oxidase inhibitors, CNS Acting Drugs, Serotonergic Drugs, Triptans, Tryptophan and Hemostasis the potential for interactoin by a variety of mechanisms (e.g., pharmacodynamic pharmacokinetic drug inhibition or anhancement, etc.) is a possibility.

**USE IN SPECIFIC POPULATIONS:**

**PREGNANCY:** Patients should be advised to notify their physician if they become pregnant or intend to become pregnant

during therapy. Fluoxetine should be used during pregnancy only if the potential benefit justifies the potential risk of the fetus.

**Nursing Mothers:** Patients should be advised to notify their physician if they intend to breast-feed an infant during therapy. Because fluoxetine is excreted in human milk, nursing while taking Fluoxetine is not recommended.

**PEDIATRIC USE:**

Fluoxetine is approved for use in pediatric patients with MDD and OCD.

**ADVERSE REACTIONS:**

The following adverse reactions can occur:

- Suicidal Thoughts and Behaviors in children, adolescents, and young adults.
- Serotonin Syndrome.
- Allergic Reactions and Rash.
- Screening Patients for Bipolar Disorder and Monitoring for Mania/Hypomania
- Seizures
- Altered Appetite and Weight
- Abnormal Bleeding (see warning and Precautions)
- Angle-Closure Glaucoma
- Hyponatremia
- Anxiety and insomnia
- QT Prolongation
- Potential for cognitive and motor impairment

**CONTRAINDICATIONS:**

**Serotonin Syndrome and MAOIs:** Do not use MAOIs intended to treat psychiatric disorders with fluoxetine or with in 5 weeks of stopping treatment with fluoxetine. Do not use floxetine with in 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start fluoxetine in a patient who is being treated with linezolid or intravenous methylene blue.

**Pimozide:** Do not use. Risk of QT Prolongation and drug interaction.

**Thioridazine:** Do not use. Risk of Qt interval prolongation and elevated thioridazine plasma levels. Do not use thioridazine within 5 weeks of discontinuing Fluoxetine. Do not use thioridazine within 5 weeks of discontinueing fluoxetine.

**Warnings & Precautions:**

**Serotonin Syndrome:** Serotonin syndrome has been reported with SSRIs abd SNRIs, including fluoxetine, both when taken alone, but especially when co-administered with other serotonergic agents (including triptans, tricyclic antidepressants fentanyl, lithium, tramadol, tryptophan, buspirone, amphetamines, and St. John\s Wort). if such symptoms occur, discontinue fluoxetine and initiate supportive treatment. It concomitant use of fluoxetine with other serotonergic drugs is clinically warranted, patients should be made aware of a potential increased risk of serotonin syndrome, particularly during treatment initiation and dose increases.

**Allergic Reactions and Rash:** Discontinue upon appearance of rash or allergic phenomena.

**Activation of Mania/Hypomania:** Screen for Bipolar Disorders and monitor for mania/hypomania.

**Seizures:** use cautiously in patients with a history of seizures or with condition that potentially lower the seizure threshold.

**Altered Appetite and Weight:** Significant weight loss has occurred.

**Abnormal Bleeding:** may increase the risk of bleeding. Use with NSAIDs, aspirin, warfarin, or other drugs that affect coagulation may potentiate the risk of gastrointestinal or other bleeding.

**Angle-Closure Glaucoma:** Angle-closure glaucoma has occurred in patients with untreated anatomically narrow angles treated with antidepressants.

**Hyponatremia:** Has been reported with fluoxetine in association with syndrome of inappropriate antidiuretic hormone (SIADH). Consider discontinuing if symptomatic hyponatremia occurs.

**QT Prolongation:** QT prolongation and ventricular arrhythmia including Torsades de pointers have been reported with fluoxetine use. Use with caution in conditions that predispose to arrhythmias or increased fluoxetine axposure. Use cautiously in patients with risk factors for Qt prolongation.

**Potential for Congitive and Motor Impairment:** Has potential to impair judgment, thinking and motor skills. Use caution when operating machinery.

**OVER DOSAGE:**

Important adverse reactions reported with fluoxetine overdose (Single or multiple drugs) include coma, delinum, ECG abnormallities (such as QT interval prolongation and ventricular tachycardia, including torsades de pointas-type arrhythmias), hypotension, mania, neuroleptic malignant syndrome-like reacitons, pyrexia, stupor and syncope.

**INSTRUCTIONS:**

Store at room temperature. After first opening, can be used up to 3 months.
Keep out of the reach and sight of children

**HOW SUPPLIED:**

Alu-PCV blister pack of 1 x 10's.

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**Manufactured By:**
**Aims Pharmaceuticals**
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