

Fluoxetine HCl Cas No. : 54910-89-3

Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) used to treat depression, anxiety disorders (panic attacks), obsessive-compulsive disorder (OCD), a certain eating disorder (bulimia), and a severe form of premenstrual syndrome (premenstrual dysphoric disorder). SSRIs work by helping to restore the balance of certain natural substances in the brain (neurotransmitters such as serotonin).

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.**Fluoxetine Hcl****CAS No. : 54910-89-3****Systematic (IUPAC) name****N-methyl-3-phenyl-3-[4- (trifluoromethyl)phenoxy]propan-1-amine****Identifiers**

CAS number 54910-89-3

ATC code N06AB03

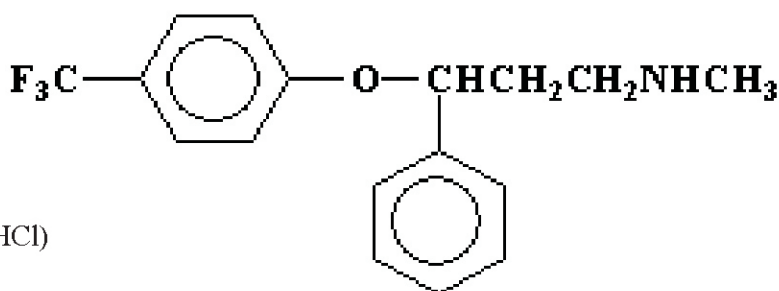
PubChem 3386

DrugBank APRD00530

ChemSpider 56589

Chemical dataFormula C₁₇H₁₈F₃NO

Mol. mass 309.3 g/mol (345.8 for •HCl)

**Pharmacokinetic data**

Bioavailability 72%

peak at 6-8 hours

Protein binding 94.5%

Metabolism Hepatic

Half life 1-3 days (acute); 4-6 days (chronic);

Active metabolite Norfluoxetine 4-16 days (acute and chronic)

Excretion Kidneys 80%, intestines 15%

WARNING

Antidepressant medications are used to treat a variety of conditions, including depression and other mental/mood disorders. These medications can help prevent suicidal thoughts/attempts and provide other important benefits. However, studies have shown that a small number of people (especially people younger than 25) who take antidepressants for any condition may experience worsening depression, other mental/mood symptoms, or suicidal thoughts/attempts. Therefore, it is very important to talk with the doctor about the risks and benefits of antidepressant medication (especially for people younger than 25), even if treatment is not for a mental/mood condition.

USES

Fluoxetine is a selective serotonin reuptake inhibitor (SSRI) used to treat depression, anxiety disorders (panic attacks), obsessive-compulsive disorder (OCD), a certain eating disorder (bulimia), and a severe form of premenstrual syndrome (premenstrual dysphoric disorder). SSRIs work by helping to restore the balance of certain natural substances in the brain (neurotransmitters such as serotonin). Fluoxetine may improve your mood, sleep, appetite, and energy level and may help restore your interest in daily living. It may decrease anxiety/unreasonable fears, persistent/troubling thoughts (obsessions), and unwanted urges that keep returning (compulsions). It may decrease the number and severity of panic attacks. Fluoxetine may lessen premenstrual symptoms such as irritability, increased appetite, and depression. It may decrease bingeing and purging behaviors in bulimia.



Taj Pharmaceuticals Ltd.
Fluoxetine Hcl

CAS No 54910-89-3

HOW TO USE

Take this medication by mouth with or without food, usually once daily or as directed by your doctor. This medication may make you either sleepy or wakeful. Therefore, depending on how this medication affects you, your doctor may direct you to take the entire dose once daily in either the morning or evening. If you are taking this medication twice a day, your doctor may direct you to take it in the morning and at noon. If you are taking fluoxetine for premenstrual problems, your doctor may direct you to take it every day of the month or just for the 2 weeks before your period through the first full day of your period. To help you remember, mark your calendar.

If you are using the liquid form of this medication, measure the dose carefully using a special measuring device/spoon. Do not use a household spoon because you may not get the correct dose.

The dosage is based on your medical condition and response to treatment. To reduce your risk of side effects, your doctor may start you at a low dose and gradually increase your dose. Follow your doctor's instructions carefully. Do not take more or less medication or take it more frequently than prescribed. Your condition will not improve any faster, and your risk of side effects will increase. Use this medication regularly in order to get the most benefit from it. To help you remember, use it at the same time(s) each day.

SIDE EFFECTS

Nausea, drowsiness, dizziness, anxiety, trouble sleeping, loss of appetite, weakness, tiredness, sweating, or yawning may occur. If any of these effects persist or worsen, tell your doctor promptly. serious side effects occur: unusual or severe mental/mood changes (such as agitation, unusual high energy/excitement, thoughts of suicide), uncontrolled movements (for example, movements of the lips/tongue), shakiness (tremor), restlessness, inability to keep still, decreased interest in sex, changes in sexual ability, blurred vision, numbness/tingling. This medication may rarely cause a very serious condition called serotonin syndrome. The risk increases when this medication is used with certain other drugs such as "triptans" used to treat migraine headaches (including sumatriptan, eletriptan), certain antidepressants including other SSRIs (such as citalopram, paroxetine) and SNRIs (such as duloxetine, venlafaxine), lithium, tramadol, tryptophan, or a certain drug to treat obesity (sibutramine). See also Drug Interactions section. Before taking this drug, tell your doctor if you take any of these medications. Serotonin syndrome may be more likely when you start or increase the dose of any of these medications. Seek immediate medical attention if you develop some of the following symptoms: hallucinations, unusual restlessness, loss of coordination, fast heartbeat, severe dizziness, unexplained fever, severe nausea/vomiting/diarrhea, twitchy muscles. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

PRECAUTIONS

Before using this medication, tell your doctor or pharmacist your medical history, especially of: personal or family history of bipolar/manic-depressive disorder, personal or family history of suicide attempts, liver problems, diabetes, low sodium in the blood, severe loss of body water (dehydration), seizures, stomach/intestinal ulcers.

This drug may make you dizzy or drowsy. Use caution while driving, using machinery, or doing any other activity that requires alertness. Avoid alcoholic beverages.

If you have diabetes, fluoxetine may affect your blood sugar levels. Monitor your blood sugar regularly and share the results with your doctor. Your doctor may need to adjust your medication, diet, and exercise when you start or stop fluoxetine. Liquid forms of this product may contain sugar and/or alcohol. Caution is advised if you have diabetes, alcohol dependence, or liver disease. Ask your doctor or pharmacist about using this product safely.

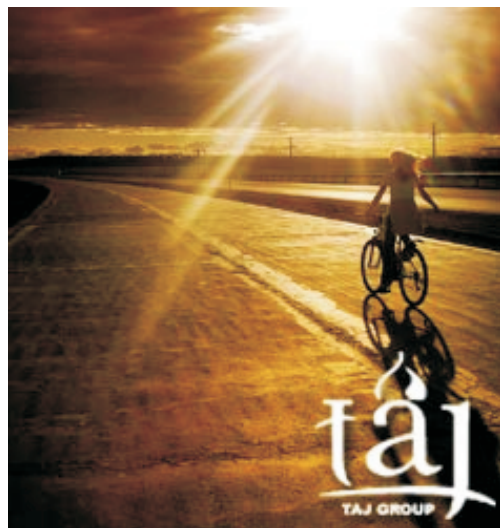


Caution is advised when using this product in the elderly because they may be more sensitive to its effects. The elderly are more likely to lose too much salt (hyponatremia), especially if they are also taking "water pills" (diuretics) with this medication.

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Also, babies born to mothers who have used this drug during the last 3 months of pregnancy may infrequently develop withdrawal symptoms such as feeding/breathing difficulties, seizures, muscle stiffness, or constant crying. If you notice any of these symptoms in your newborn, tell the doctor promptly.

MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.



STORAGE

Store at room temperature between 59-86 degrees F (15-30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

Take fluoxetine exactly as it was prescribed for you. Do not take the medication in larger amounts, or take it for longer than recommended by your doctor. Follow the directions on your prescription label.

Do not break, chew, or open an extended-release capsule. Swallow the pill whole. It is specially made to release medicine slowly in the body. Breaking the pill would cause too much of the drug to be released at one time.

Measure the liquid form of fluoxetine with a special dose-measuring spoon or cup, not a regular table spoon. If you do not have a dose-measuring device, ask your pharmacist where you can get one.

It may take 4 weeks or longer before you start feeling better. Do not stop using fluoxetine without first talking to your doctor. You may have unpleasant side effects if you stop taking this medication suddenly.

To treat premenstrual dysphoric disorder, the usual dose of fluoxetine is once daily while you are having your period, or 14 days before you expect your period to start.

DRUG DESCRIPTION

Fluoxetine capsules and fluoxetine oral solution is a selective serotonin reuptake inhibitor for oral administration.

It is also marketed for the treatment of premenstrual dysphoric disorder fluoxetine hydrochloride. It is designated (±)-N-methyl-3-phenyl-3-[(a,a,a-trifluoro-p-tolyl)oxy]propylamine hydrochloride and has the empirical formula of C₁₇H₁₈F₃NO•HCl.

Its molecular weight is 345.79. Fluoxetine hydrochloride is a white to off-white crystalline solid with a solubility of 14 mg/mL in water. Fluoxetine hydrochloride equivalent to 10 mg (32.3 μmol), 20 mg (64.7 μmol), or 40 mg (129.3 μmol) of fluoxetine.



The oral solution contains fluoxetine hydrochloride equivalent to 20 mg per 5 mL (64.7 µmol) of fluoxetine. It also contains alcohol 0.23%, benzoic acid, flavoring agent, glycerin, purified water, and sucrose.

Fluoxetine is an antidepressant in a group of drugs called selective serotonin reuptake inhibitors (SSRIs). Fluoxetine affects chemicals in the brain that may become unbalanced and cause depression, panic, anxiety, or obsessive-compulsive symptoms.

Fluoxetine is used to treat major depressive disorder, bulimia nervosa (an eating disorder) obsessive-compulsive disorder, panic disorder, and premenstrual dysphoric disorder

INTERACTION

Before taking fluoxetine, tell your doctor if you are using any of the following medicines:

- * alprazolam
- * clozapine
- * digitoxin
- * flecainide
- * haloperidol
- * seizure medication such as phenytoin or carbamazepine
- * tryptophan
- * vinblastine
- * a blood thinner such as warfarin
- * almotriptan , frovatriptan , sumatriptan , naratriptan , rizatriptan , or zolmitriptan ; or}
- * any other antidepressants such as amitriptyline , escitalopram , imipramine , sertraline , and others.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
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