

Fluvoxamine Maleate Cas No. : 61718-82-9

Fluvoxamine maleate is a white to off white, odorless, crystalline powder which is sparingly soluble in water, freely soluble in ethanol and chloroform and practically insoluble in diethyl ether.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Fluvoxamine Maleate

CAS No. : 61718-82-9



Molecular Weight 434.41
Melting point 120-121.5 °C

Systematic (IUPAC) name

(Z)-5-methoxy-1-[4-(trifluoromethyl)phenyl]pentan-1-one O-2-aminoethyl oxime

Identifiers

CAS number 61718-82-9
ATC code N06AB08
PubChem 5324346
DrugBank APRD00425
ChemSpider 4481878

Chemical data

Formula C₁₅H₂₁F₃N₂O₂
Mol. mass 318.335

Pharmacokinetic data

Bioavailability 77%
Metabolism Hepatic
Half life 15.6 hours
Excretion Renal

DOSAGE

Take this medication only as directed by your doctor.

Fluvoxamine may be taken with or without food.

* If you miss a dose...

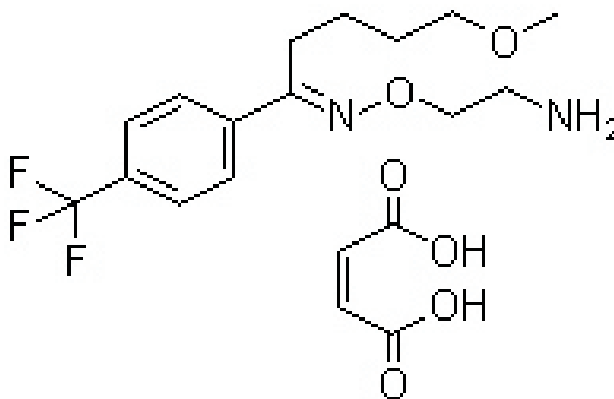
If you are taking 1 dose a day, skip the missed dose and go back to your regular schedule. If you are taking 2 doses a day, take the missed dose as soon as possible, then go back to your regular schedule. Never take 2 doses at the same time.

SIDE EFFECTS

Side effects cannot be anticipated. If any develop or change in intensity, tell your doctor immediately. More common side effects may include:

Abnormal ejaculation, agitation, anxiety, diarrhea, dizziness, dry mouth, headache, indigestion, insomnia, nausea, nervousness, sleepiness, sweating, tremor, vomiting, weakness, weight loss

Suicidal thoughts or actions: Persons taking fluvoxamine may be more likely to think about killing themselves or actually try to do so, especially when fluvoxamine is first started or the dose is changed. People close to persons taking fluvoxamine can help by paying attention to changes in user's moods or actions.





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**Fluvoxamine
Maleate**

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Contact your healthcare professional right away if someone using fluvoxamine talks about or shows signs of killing him or herself. If you are taking fluvoxamine yourself and you start thinking about killing yourself, tell your healthcare professional about this side effect right away.

Stopping fluvoxamine: Do not stop taking citalopram suddenly because you could get side effects. Your healthcare professional will slowly decrease your dose.

Bleeding problems: fluvoxamine may cause bleeding problems, especially if taken with aspirin, NSAIDs (nonsteroidal anti-inflammatory drugs, such as ibuprofen and naproxen), or other drugs that affect bleeding.

Mania: You may become unusually hyperactive, excitable or elated.

Seizures: You may experience a seizure (convulsion), even if you are not taking fluvoxamine close in time with an MAOI.

Pregnancy: Tell your healthcare professional if you are or may be pregnant (see FDA Alert [06/2006] above). In addition to the issue described in the alert, babies delivered to mothers taking fluvoxamine late in pregnancy have developed problems, such as difficulty breathing and feeding.

Sexual problems: You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).

Other side effects include nausea, vomiting, upset stomach, difficulty sleeping, nervousness, shakiness, sweating, weakness, decreased appetite, and sleepiness.

Tell your healthcare professional about all your medical conditions, especially liver or kidney disease. Tell your healthcare professional if you are breast-feeding or plan to breast-feed your baby.

PRECAUTIONS

Activation of Mania/Hypomania: During premarketing studies involving primarily depressed patients, hypomania or mania occurred in approximately 1% of patients treated with fluvoxamine. Activation of mania/hypomania has also been reported in a small proportion of patients with major affective disorder who were treated with other marketed antidepressants. As with all antidepressants, fluvoxamine maleate should be used cautiously in patients with a history of mania.

Seizures: During premarketing studies, seizures were reported in 0.2% of fluvoxamine-treated patients. Fluvoxamine maleate should be used cautiously in patients with a history of seizures. It should be discontinued in any patient who develops seizures.

Suicide: The possibility of a suicide attempt is inherent in patients with depressive symptoms, whether these occur in primary depression or in association with another primary disorder such as OCD. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions for fluvoxamine maleate should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

Use in Patients with Concomitant Illness: Closely monitored clinical experience with fluvoxamine maleate in patients with concomitant systemic illness is limited. Caution is advised in administering fluvoxamine maleate to patients who have diseases or conditions that could affect hemodynamic responses or metabolism.



Interference with Cognitive or Motor Performance: Since any psychoactive drug may impair judgement, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles, until they are certain that fluvoxamine maleate therapy does not adversely affect their ability to engage in such activities.

DRUG DESCRIPTION

Fluvoxamine is a selective serotonin reuptake inhibitor (SSRI) used to treat obsessive-compulsive disorder.

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Fluvoxamine is prescribed for obsessive-compulsive disorder. An obsession is marked by continual, unwanted thoughts that prevent proper functioning in everyday living. Compulsive behavior is typified by ritualistic actions such as repetitious washing, repeating certain phrases, completing steps in a process over and over, counting and recounting, checking and rechecking to make sure that something has not been forgotten, excessive neatness, and hoarding of useless items.

Fluvoxamine is thought to work by increasing levels of serotonin, a brain chemical associated with mood and thinking. It belongs to a class of drugs known as selective serotonin re-uptake inhibitors (SSRIs), which also includes antidepressants such as fluoxetine and paroxetine.



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.

Information: The information on this web page is provided to help you to work safely, but it is intended to be an overview of hazards, not a replacement for a full Material Safety Data Sheet (MSDS). MSDS forms can be downloaded from the web sites of many chemical suppliers. Also that the information on the PTCL Safety web site, where this page was hosted, has been copied onto many other sites, often without permission. If you have any doubts about the veracity of the information that you are viewing, or have any queries, please check the URL that your web browser displays for this page. If the URL begins "www.tajapi.com/www/Denatonium Benzoate.htm/" the page is maintained by the Safety Officer in Physical Chemistry at Oxford University. If not, this page is a copy made by some other person and we have no responsibility for it.

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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