Venlafaxine is an antidepressant (serotonin-norepinephrine reuptake inhibitor type-SNRI) used in the treatment of depression, anxiety, an panic attacks. It works by restoring the balance of natural substances in the brain.

Active Pharmaceuticals Ingredients Manufacturers



Taj Pharma PDI



Taj Pharmaceuticals Ltd.

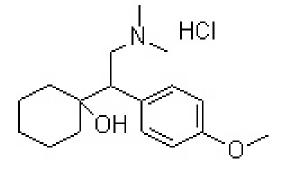
Venlafaxine Hcl

CAS No.: 99300-78-4



Chemical data

Molecular Formula C17H27NO2.HCl;C17H28ClNO2 Molecular Weight 313.87 CAS Registry Number 99300-78-4 ATC code N06AX16 PubChem 5656 DrugBank APRD00125 ChemSpider 56641



Pharmacokinetic data

Bioavailability 45% Protein binding 27% Metabolism Hepatic

Half life 5 ± 2 hours (parent compound); 11 ± 2 hours (active metabolite)

Excretion Renal

DOSAGE

The number of capsules or tablets that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on your special needs.

For mental depression:

Adults—At first, 75 milligrams (mg) a day, taken in one dose in the morning or evening. Your doctor may increase your dose if needed. However, the dose is usually not more than 225 mg a day.

Children—Use and dose must be determined by your doctor.

For oral tablet dosage form:

Adults—At first, a total of 75 mg a day, taken in smaller doses two or three times during the day. Your doctor may increase your dose if needed. However, the dose is usually not more than 375 mg a day.

Children up to 18 years of age—Use and dose must be determined by your doctor.

For anxiety:

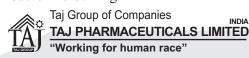
For oral extended-release capsule dosage form:

Adults—At first, 75 mg a day, taken in one dose in the morning or evening. Your doctor may increase your dose if needed. However, the dose is usually not more than 225 mg per day.

Children—Use and dose must be determined by your doctor

SIDE EFFECTS

- * More common: Changes in vision, such as blurred vision; decrease in sexual desire or ability; headache
- * Less common: Chest pain; fast or irregular heartbeat; mood or mental changes; ringing or buzzing in ears
- * Rare: Convulsions (seizures); itching or skin rash; lightheadedness or fainting, especially when getting up suddenly from a sitting or lying position; lockjaw; menstrual changes; problems in urinating or in holding urine; swelling; talking, feeling, and acting with excitement and activity you cannot control; trouble in breathing



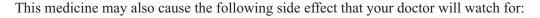




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* More common: High blood pressure

Other side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. However, check with your doctor if any of the following side effects continue or are bothersome:

- * More common: Abnormal dreams; anxiety or nervousness; chills; constipation; diarrhea; dizziness; drowsiness; dryness of mouth; heartburn; increased sweating; loss of appetite; nausea; stuffy or runny nose; stomach pain or gas; tingling, burning, or prickly sensations; trembling or shaking; trouble in sleeping; unusual tiredness or weakness; vomiting; weight loss
- * Less common: Change in sense of taste; muscle tension; yawning

After you stop using this medicine, your body may need time to adjust. The length of time this takes depends on the amount of medicine you were using and how long you used it. During this period of time check with your doctor if you notice any of the following side effects:

* Changes in dreaming; dizziness; dryness of mouth; headache; increased sweating; nausea; nervousness; trouble in sleeping; unusual tiredness or weakness

PRECAUTIONS

Before taking venlafaxine, tell your doctor if you are allergic to it; or if you have any other allergies.

Before using this medication, tell your doctor your medical history, especially of: bleeding problems, certain mental/mood conditions (bipolar disorder), dehydration, glaucoma, heart problems (high blood pressure, unstable heart disease, heart failure, recent heart attack), high cholesterol, kidney disease, liver disease, seizures, thyroid problems, untreated mineral imbalance (e.g. hyponatremia).

This drug may make you dizzy, drowsy or cause blurred vision; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages.

Though uncommon, depression can lead to thoughts or attempts of suicide. Tell your doctor immediately if you have any suicidal thoughts, worsening depression, or any other mental/mood changes (including new or worsening anxiety, agitation, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, rapid speech). Keep all medical appointments so your healthcare professional can monitor your progress closely and adjust/change your medication if needed.

Caution is advised when using this drug in the elderly because they may be more sensitive to its effects. The elderly are more likely to develop a type of mineral imbalance (hyponatremia), especially if they are also taking "water pills" or diuretics with this medication. This medication should be used only when clearly needed during pregnancy.

However, do not stop taking this medication unless your doctor directs you to do so. Report any such symptoms to your doctor promptly. This medication passes into breast milk and may have undesirable effects on a nursing infant. Breast-feeding is not recommended while using this drug. Consult your doctor before breast-feeding.







DRUG DESCRIPTION

Venlafaxine hydrochloride is a white to off-white crystalline solid with a solubility of 572 mg/mL in water (adjusted to ionic strength of 0.2 M with sodium chloride). It s octanol: water (0.2 M sodium chloride) partition coefficient is 0.43.

Venlafaxine hydrochloride is formulated as an extended-release capsule for once-a-day oral administration. Drug release is controlled by diffusion through the coating membrane on the spheroids and is not pH dependent. Capsules contain venlafaxine hydrochloride equivalent to 37.5 mg, 75 mg, or 150 mg venlafaxine. Inactive ingredients consist of cellulose, ethylcellulose, gelatin, hypromellose, iron oxide, and titanium dioxide.



(Venlafaxine) is an antidepressant medication. It affects chemicals in your brain that may become unbalanced and cause depression. Venlafaxine is used to relieve symptoms of depression such as feelings of sadness, worthlessness, or guilt; loss of interest in daily activities; changes in appetite; tiredness; sleeping too much; insomnia; and thoughts of death or suicide. Venlafaxine is also used to relieve symptoms of generalized anxiety disorder. It is also being prescribed by some doctors as Migraine preventive.

Venlafaxine is used to treat depression. Venlafaxine extended-release (long-acting) capsules are also used to treat generalized anxiety disorder (excessive worrying that is difficult to control), social anxiety disorder (extreme fear of interacting with others or performing in front of others that interferes with normal life), and panic disorder (sudden, unexpected attacks of extreme fear and worry about these attacks). Venlafaxine is in a class of medications called selective serotonin and norepinephrine reuptake inhibitors (SNRIs). It works by increasing the amounts of serotonin and norepinephrine, natural substances in the brain that help maintain mental balance.

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

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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:

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

This leaflet was prepared by

Taj Pharmaceuticals Limited,

Mumbai (India).

MPSTJ278

Last revised: 29 August 2009

