Taj Pharmaceuticals Ltd.

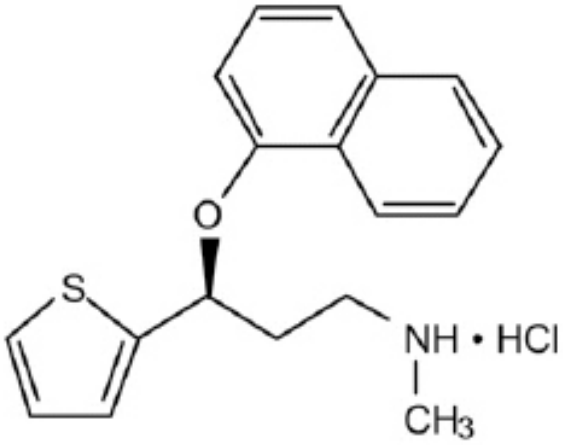
Duloxetine Hcl

CAS No. : 136434-34-9

Systematic (IUPAC) name
(+)-(S)-N-Methyl-3-(naphthalen-1-yloxy)-
3-(thiophen-2-yl)propan-1-amine

Identifiers

CAS number 116539-59-4 (free base). 136434-34-9 (hydrochloride)
ATC code N06AX21
PubChem 60835
DrugBank APRD00060
ChemSpider 54822



Chemical data

Formula C18H19NOS
Mol. mass 297.41456 g/mol
SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability ~ 50% (32% to 80%)
Protein binding ~ 95%
Metabolism Liver, two P450 isozymes, CYP2D6 and CYP1A2.
Half life 12,1 hours
Excretion 70% in urine, 20% in feces

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

Duloxetine is used to treat major depression and anxiety. It is also used to relieve nerve pain (peripheral neuropathy) in people with diabetes.

This medication is a serotonin-norepinephrine reuptake inhibitor (SNRI) that works by helping to restore the balance of certain natural substances in the brain (neurotransmitters). Duloxetine may improve your mood, sleep, appetite, and energy level, and decrease nervousness. It can also decrease pain caused by nerve damage.

HOW TO USE

Read the Medication Guide provided by your pharmacist before you start using duloxetine and each time you get a refill. If you have any questions, consult your doctor or pharmacist.

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Take this medication by mouth with or without food, usually 1 or 2 times a day or as directed by your doctor. Swallow the capsule whole. Do not crush or chew the capsule or mix the contents with food or liquid. 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.

It is important to continue taking this medication even if you feel well. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when the drug is suddenly stopped. Your dose may need to be gradually decreased.

SIDE EFFECTS

Nausea, dry mouth, constipation, loss of appetite, tiredness, drowsiness, dizziness, increased sweating, blurred vision, or yawning may occur. If any of these effects persist or worsen, tell your doctor promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: fainting, unusual or severe mental/mood changes (e.g., nervousness, unusual high energy/excitement, rare thoughts of suicide), shakiness (tremor), decreased interest in sex, changes in sexual ability, difficulty urinating, change in the amount of urine, weight loss.

Tell your doctor immediately if any of these rare but very serious side effects occur: stomach pain, bloody/black/tarry stools, vomit that looks like coffee grounds, easy bruising/bleeding, muscle weakness/cramps, yellowing eyes/skin, dark urine, seizures, unusual tiredness, fast/irregular/pounding heartbeat.

PRECAUTIONS

Before using this medication, tell your doctor or pharmacist your medical history, especially of: personal or family history of psychiatric disorders (e.g., bipolar/manic-depressive disorder), personal or family history of suicide attempts, diabetes, glaucoma (narrow-angle), kidney disease, stomach problems (e.g., bleeding or slow emptying of the stomach), low sodium in the blood, severe loss of body water (dehydration), drug or alcohol abuse, seizure disorder.

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. Drinking alcohol can also increase your risk of liver problems.

To reduce dizziness and lightheadedness, get up slowly when rising from a sitting or lying position. Dizziness is more common when you start taking this medication and when your dose is increased.

If you have diabetes, duloxetine 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 duloxetine.

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.

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 at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

Diabetic Peripheral Neuropathic Pain
Adults

PO 60 mg once daily without regard to meals.Fibromyalgia
Adults
PO Start with 30 mg once daily for 1 wk. The dose may be increased to 60 mg once daily after 1 wk.
Generalized Anxiety Disorder
Adults
PO Start with 30 or 60 mg once daily without regard to meals. If the starting dosage is 30 mg once daily, the dosage may be increased to 60 mg once daily after 1 wk. Additional dosage increases should be in increments of 30 mg once daily (max, 120 mg once daily). There is no evidence that doses of more than 60 mg once daily confer additional benefit.
Major Depressive Disorder
Adults
PO 40 mg daily (given as 20 mg twice daily) to 60 mg daily (given once daily or as 30 mg twice daily) without regard to meals.
General Advice

* Advise patient to swallow capsule whole and not to crush, chew, or open capsule.
* Assess patients with major depressive disorders periodically to determine the need for maintenance treatment and appropriateness of dose.
* Efficacy of duloxetine in the treatment of generalized anxiety disorder beyond 10 wk has not been studied. Periodically evaluate patients for long-term usefulness of the drug.
* Efficacy of duloxetine in the management of diabetic peripheral neuropathic pain has not been evaluated beyond 12 wk.
* Efficacy of duloxetine in the management of fibromyalgia has not been evaluated beyond 3 months.

DRUG DESCRIPTION

Duloxetine Hydrochlorideis a selective serotonin and norepinephrine reuptake inhibitor (SSNRI) for oral administration. Its chemical designation is (+)-(S)-N-methyl-γ-(1-naphthyloxy)-2-thiophenepropylamine hydrochloride. The empirical formula is C18H19NOS•HCl, which corresponds to a molecular weight of 333.88.

Duloxetine hydrochloride is a white to slightly brownish white solid, which is slightly soluble in water.

Each capsule contains enteric-coated pellets of 22.4, 33.7, or 67.3 mg of duloxetine hydrochloride equivalent to 20, 30, or 60 mg of duloxetine, respectively. These enteric-coated pellets are designed to prevent degradation of the drug in the acidic environment of the stomach. Inactive ingredients include FD&C Blue No. 2, gelatin, hypromellose, hydroxypropyl methylcellulose acetate succinate, sodium lauryl sulfate, sucrose, sugar spheres, talc, titanium dioxide, and triethyl citrate. The 20 and 60 mg capsules also contain iron oxide yellow.

Duloxetine HCl is used to treat major depression—a disorder marked by continuing, serious, and overwhelming feelings of depression that interfere with daily functioning. Symptoms may include major changes in appetite or sleep habits; lack of interest in social or work life; feelings of sadness, guilt, or worthlessness; fatigue; difficulty concentrating or making decisions; and suicidal thoughts or attempted suicide.

Duloxetine HCl is also used to treat diabetic peripheral neuropathy, a painful nerve disorder associated with diabetes that affects the hands, legs, and feet.

Duloxetine HCl is thought to work by correcting an imbalance of two brain chemicals known to influence mood—serotonin and norepinephrine. It belongs to a class of antidepressants called selective serotonin and norepinephrine reuptake inhibitors

INTERACTION

Never take Duloxetine HCl with MAO inhibitors (see "Most important fact about Duloxetine hydrochloride) or the drug thioridazine. Consult your doctor first before taking drugs that act on the central nervous system, such as antipsychotics, narcotic painkillers, sleep inducers, or tranquilizers.

Due to the possibility of liver damage, do not take Duloxetine HCl if you use alcohol more than occasionally.

If Duloxetine HCl is taken with certain other drugs, the effects of either could be increased, decreased, or altered. It is especially important to check with your doctor before combining Duloxetine HCl with the following:

Antibiotics known as quinolones, such as ciprofloxacin
Antidepressants known as tricyclics, such as amitriptyline
Antidepressants that raise serotonin levels
Antipsychotic medication known as phenothiazines
Flecainide
Fluvoxamine
Propafenone
Quinidine

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

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91 022 30601000.
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