

Paroxetine Cas No. : 61869-08-7

Paroxetine is a selective serotonin reuptake inhibitor (SSRI) used to treat depression, panic attacks, obsessive-compulsive disorder (OCD), anxiety disorders, post-traumatic stress disorder, and a severe form of premenstrual syndrome (premenstrual dysphoric disorder).

Active Pharmaceuticals Ingredients Manufacturers

Taj Pharmaceuticals Ltd.**Paroxetine****CAS No. : 61869-08-7**

Paroxetine is a selective serotonin reuptake inhibitor (SSRI) antidepressant.

Paroxetine is primarily used to treat the symptoms of major depression, obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD), panic disorder, generalized anxiety disorder (GAD), social phobia/social anxiety disorder, and premenstrual dysphoric disorder (PMDD).

Systematic (IUPAC) name

(3S,4R)- 3-([benzo[d][1,3]dioxol-5-yloxy] methyl)- 4-(4-fluorophenyl) piperidine

Identifiers

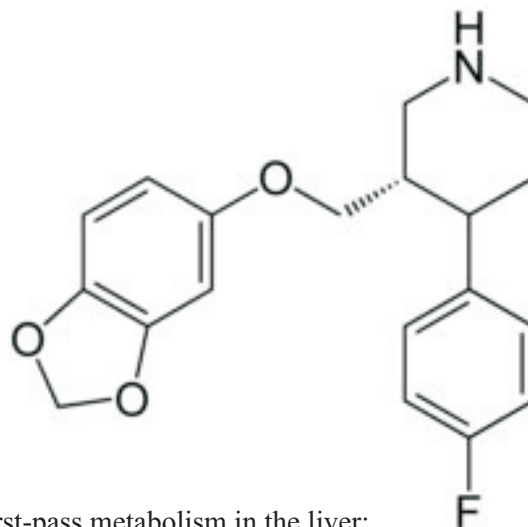
ATC code N06AB05
 PubChem 43815
 DrugBank APRD00364
 ChemSpider 39888

Chemical data

Formula C₁₉H₂₀FNO₃
 Mol. mass 329.3
 SMILES eMolecules & PubChem

Pharmacokinetic data

Bioavailability Completely absorbed from GI, but extensive first-pass metabolism in the liver;
 Tmax 4.9 (with meals) to 6.4 hours (fasting)
 Protein binding 93–95%
 Metabolism Extensive, hepatic (mostly CYP2D6-mediated)
 Half life 24 hours (range 3–65 hours)
 Excretion 64% in urine, 36% in bile
 Therapeutic considerations
 License data
 Pregnancy cat.
 Legal status
 Prescription only
 Routes Oral

**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.



Taj Pharmaceuticals Ltd.
Paroxetine

CAS No 61869-08-7

USES

Paroxetine is a selective serotonin reuptake inhibitor (SSRI) used to treat depression, panic attacks, obsessive-compulsive disorder (OCD), anxiety disorders, post-traumatic stress disorder, 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). Paroxetine 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. Paroxetine may lessen premenstrual symptoms such as irritability, increased appetite, and depression.

HOW TO USE

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

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. Swallow the medication whole. Do not crush or chew this medication.

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 each day.

If you are taking paroxetine 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.

It is important to continue taking this medication as prescribed even if you feel well. Do not stop taking this medication without first consulting your doctor.

SIDE EFFECTS

Nausea, drowsiness, dizziness, trouble sleeping, loss of appetite, weakness, tiredness, dry mouth, sweating, yawning, or headache 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: unusual or severe mental/mood changes (e.g., agitation, thoughts of suicide), 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 (e.g., sumatriptan, eletriptan), certain antidepressants including other SSRIs (e.g., citalopram, fluoxetine) and SNRIs (e.g., duloxetine, venlafaxine), lithium, tramadol, tryptophan, or a certain drug to treat obesity (sibutramine). 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.



For males, in the very unlikely event you have a painful or prolonged erection lasting 4 or more hours, stop using this drug and seek immediate medical attention, or permanent problems could occur.

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, severe dizziness, trouble breathing.

PRECAUTIONS

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

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, kidney problems, low sodium in the blood, severe loss of body water (dehydration), seizures, stomach/intestinal ulcers, glaucoma (narrow-angle type).

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.

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.

This medication is not recommended for use during pregnancy. 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 at or below 77 degrees F (25 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

DOSAGE

The recommended dose is 20-60 mg daily of immediate release tablets or 12.5-75 mg daily using controlled release tablets. Paroxetine is given as a single daily dose, usually in the morning. As with all anti-depressants, the full effect may not occur until after a few weeks of therapy. Doses for obsessive-compulsive disorders and panic disorders are often higher than those for depression. Doses often are adjusted to find the optimal dose. Elderly patients, debilitated persons, and patients with certain kidney or liver diseases may need lower doses because they metabolize and eliminate paroxetine more slowly and, therefore, are prone to develop high blood levels and toxicity.

Take paroxetine exactly as it was prescribed for you. Do not take paroxetine in larger amounts, or take it for longer than recommended by your doctor. Your doctor may occasionally change your dose to make sure you get the best results from the medication.

Try to take paroxetine at the same time each day. Follow the directions on your prescription label.

Do not crush, chew, or break a controlled-release tablet. 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.



Shake the liquid form of paroxetine well just before you measure a dose. To be sure you get the correct dose, measure the liquid with a marked measuring spoon or medicine cup, not with a regular table spoon. If you do not have a dose-measuring device, ask your pharmacist for one.

It may take up to 4 weeks of using this medicine before your symptoms improve. For best results, keep using the medication as directed. Talk with your doctor if your symptoms do not improve after 4 weeks of treatment.

You may have withdrawal symptoms (such as agitation, dizziness, numbness or tingling, ringing in your ears, confusion, or behavior changes) after you stop taking paroxetine. Do not stop taking this medication suddenly without first talking to your doctor.

DRUG DESCRIPTION

paroxetine is an orally administered psychotropic drug with a chemical structure unrelated to other selective serotonin reuptake inhibitors or to tricyclic, tetracyclic, or other available antidepressant or antipanic agents. It is the hydrochloride salt of a phenylpiperidine compound identified chemically as (-)-trans-4R-(4'-fluorophenyl)-3S-[(3',4'-methylenedioxyphenoxy) methyl] piperidine hydrochloride hemihydrate and has the empirical formula of $C_{19}H_{20}FNO_3 \cdot HCl \cdot 1/2H_2O$. The molecular weight is 374.8 (329.4 as free base).

Paroxetine hydrochloride is an odorless, off-white powder, having a melting point range of 120° to 138°C and a solubility of 5.4 mg/mL in water.

Each enteric, film-coated, controlled-release tablet contains paroxetine hydrochloride equivalent to paroxetine as follows: 12.5 mg–yellow, 25 mg–pink, 37.5 mg–blue. One layer of the tablet consists of a degradable barrier layer and the other contains the active material in a hydrophilic matrix.

Inactive ingredients consist of hypromellose, polyvinylpyrrolidone, lactose monohydrate, magnesium stearate, silicon dioxide, glyceryl behenate, methacrylic acid copolymer type C, sodium lauryl sulfate, polysorbate 80, talc, triethyl citrate, titanium dioxide, polyethylene glycols, and 1 or more of the following colorants: Yellow ferric oxide, red ferric oxide, D&C Red No. 30 aluminum lake, FD&C Yellow No. 6 aluminum lake, D&C Yellow No. 10 aluminum lake, FD&C Blue No. 2 aluminum lake.

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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