

Quetiapine Fumarate Cas No. : 111974-69-7

This medication is used with or without other medications to treat certain mental/mood conditions (e.g., bipolar disorder, schizophrenia). Quetiapine is known as an anti-psychotic drug (atypical type). It works by helping to restore the balance of certain natural chemicals (neurotransmitters) in the brain.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.**Quetiapine Fumarate****CAS No. : 111974-69-7****Systematic (IUPAC) name**

2-(2-(4-dibenzo[b,f][1,4]thiazepine- 11-yl-1-piperazinyloxy)ethoxy)ethanol

Identifiers

CAS number 111974-69-7

ATC code N05AH04

PubChem 5002

DrugBank APRD00675

ChemSpider 4827

Chemical dataFormula C₂₁H₂₅N₃O₂S

Mol. mass 383.5099 g/mol

SMILES eMolecules & PubChem

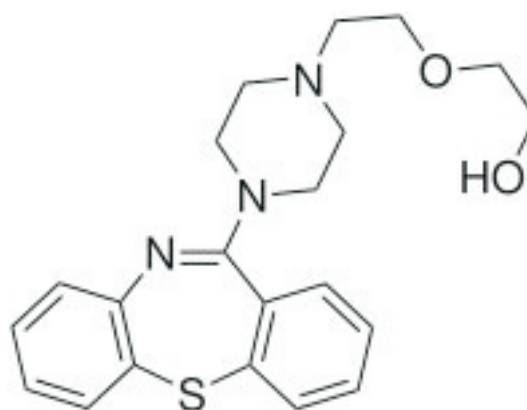
Pharmacokinetic data

Bioavailability 9%

Metabolism Hepatic

Half life 6 hours

Excretion Renal



Quetiapine is indicated for the treatment of schizophrenia, depressive episodes associated with bipolar disorder, acute manic episodes associated with bipolar I disorder (as either monotherapy or adjunct therapy to lithium or divalproex), and maintenance treatment of bipolar I disorder (as adjunct therapy to lithium or divalproex). It is sometimes used off-label, often as an augmentation agent, to treat such conditions as obsessive-compulsive disorder, post-traumatic stress disorder, restless legs syndrome, autism, alcoholism Tourette syndrome and has been used by physicians as a sedative for those with sleep disorders or anxiety disorders

WARNING

There may be a slightly increased risk of serious, possibly fatal side effects (e.g., stroke, heart failure) when this medication is used in elderly patients with dementia. This medication is not approved for the treatment of dementia-related behavior problems. Discuss the risks and benefits of this medication, as well as other effective and possibly safer treatments for dementia-related behavior problems, with the doctor.

USES

This medication is used with or without other medications to treat certain mental/mood conditions (e.g., bipolar disorder, schizophrenia). Quetiapine is known as an anti-psychotic drug (atypical type). It works by helping to restore the balance of certain natural chemicals (neurotransmitters) in the brain.

This medication can decrease hallucinations and improve your concentration. It helps you to think more clearly and positively about yourself, feel less nervous, and take a more active part in everyday life. Quetiapine can help prevent severe mood swings or decrease how often mood swings occur.



Taj Pharmaceuticals Ltd.

Quetiapine Fumarate

CAS No 111974-69-7



HOW TO USE

Take this medication by mouth with or without food, usually 2 or 3 times daily or as directed by your doctor. Dosage is based on your medical condition and response to therapy. Your doctor will start you at a low dose and gradually increase the dose to reduce the dizziness and lightheadedness that may occur when you first start to take this drug. It may take several weeks to notice the full benefit of this drug.

Use this medication regularly in order to get the most benefit from it. To help you remember, use it at the same times each day. If you stop taking quetiapine for more than one week, notify your doctor. If you restart the drug, you may need to start at a low dose and gradually increase the dose again.

Continue taking this medication exactly as prescribed, even if you are feeling better and thinking more clearly. Do not stop taking this medication without first consulting your doctor. Some conditions may become worse when the drug is suddenly stopped.

This medication may cause dependence, especially if it has been used regularly for an extended time or if it has been used in high doses. In such cases, withdrawal reactions (such as trouble sleeping, nausea, diarrhea, irritability) may occur if you suddenly stop this drug. To prevent withdrawal when stopping extended/regular treatment with this drug, gradually reduce the dosage as directed. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately.

SIDE EFFECTS

Constipation, drowsiness, dizziness, headache, stomach pain/upset, tiredness, weight gain, nasal congestion, or dry mouth may occur. If any of these side effects persist or worsen, notify your doctor.

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.

Quetiapine may rarely cause a condition known as tardive dyskinesia. In some cases, this condition may be permanent. Tell your doctor immediately if you develop any unusual/uncontrolled movements (especially of the face, lips, mouth, tongue, arms or legs).

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

This drug may infrequently cause a serious (rarely fatal) nervous system disorder (neuroleptic malignant syndrome). Seek immediate medical attention if you notice any of the following rare but very serious side effects: muscle stiffness, high fever, increased sweating, fast heartbeat, mental/mood changes, change in the amount of urine.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

PRECAUTIONS

Before taking quetiapine, 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: Alzheimer's disease, low blood pressure, disease of the blood vessels in the brain (e.g., stroke), blood disorders (e.g., leukopenia, neutropenia), a severe loss of body water (dehydration), certain eye problems (cataracts), liver disease, seizures, trouble swallowing, thyroid problems.



Also tell your doctor or pharmacist if you or a family member has a history of the following: alcohol/drug abuse, diabetes, heart disease (e.g., ischemic heart disease, heart failure, heart rhythm problems), high blood cholesterol/triglyceride levels, high blood pressure, obesity.

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. Keep all medicines away from children and pets.

DOSAGE

Acute Bipolar Mania

Adults

PO 100 mg/day in 2 divided doses on day 1; increase to 400 mg/day on day 4 in increments of up to 100 mg/day in 2 divided doses. Further dosage adjustments of up to 800 mg/day by day 6 should be in increments of no more than 200 mg/day.

Depression

Adults

PO Start with 50 mg once daily at bedtime. Increase to 100 mg on day 2, 200 mg on day 3, and 300 mg on day 4. If indicated, the dose may be increased to 400 mg on day 5 and 600 mg on day 8.

Maintenance in Bipolar I Disorder

Adults

PO Generally, in the maintenance phase, patients are continued on the same dose on which they were stabilized during dose stabilization.

Schizophrenia

Adults

PO 25 mg twice daily initially; may increase in increments of 25 to 50 mg twice daily to 3 times daily on days 2 and 3 to target range of 300 to 400 mg/day by day 4. Increase dose every 2 days by 25 to 50 mg twice daily as indicated.

Therapeutic dose range is 150 to 750 mg/day.

Adults

PO Start with 300 mg once daily, preferably in the evening. Dose increases can be made at daily intervals in increments of up to 300 mg/day. Dosages above 800 mg/day have not been evaluated.

Elderly/Hepatic Function Impairment

Adults

PO Start with 25 mg/day; increase in daily increments of 25 to 50 mg/day to an effective dose.

General Advice

* Safety of dosages higher than 800 mg/day has not been evaluated.

* Take without regard to meals. Take with food if stomach upset occurs.

* Long-term use (more than 6 wk) not evaluated. Periodically reevaluate usefulness.

* When restarting patients who have had an interval of less than 1 wk off quetiapine, resume maintenance dose. If the interval is more than 1 wk, follow initial titration period.



- * tablets should be swallowed whole and not split, chewed, or crushed.
- * should be taken without food or with a light meal (about 300 calories).
- * Use immediate-release tablet for schizophrenic patients requiring less than 200 mg per dose of during the initial titration.
- * Start schizophrenic elderly patients and/or patients with hepatic function impairment on the immediate-release formulation. Dose can be incrementally increased daily. When an effective dose has been reached, the patient may switch to an equivalent total daily dose of the ER formulation.
- * Schizophrenic patients currently treated with divided doses of the immediate-release formulation may be switched to equivalent total daily doses of the ER formulation taken once daily.
- * Consideration should be given to a slower rate of dose titration and a lower target dose in elderly patients and in patients who are debilitated or who are predisposed to hypotension.

DRUG DESCRIPTION

Quetiapine fumarate is a psychotropic agent belonging to a chemical class, the dibenzothiazepine derivatives. The chemical designation is 2-[2-(4-dibenzo [b,f] [1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]-ethanol fumarate (2:1) (salt). It is present in tablets as the fumarate salt. All doses and tablet strengths are expressed as milligrams of base, not as fumarate salt. Its molecular formula is $C_{42}H_{50}N_6O_4S_2 \cdot C_4H_4O_4$ and it has a molecular weight of 883.11 (fumarate salt). Quetiapine fumarate is a white to off-white crystalline powder which is moderately soluble in water. Inactive ingredients are povidone, dibasic dicalcium phosphate dihydrate, microcrystalline cellulose, sodium starch glycolate, lactose monohydrate, magnesium stearate, hypromellose, polyethylene glycol and titanium dioxide.

Quetiapine fumarate is prescribed for the treatment of schizophrenia, a mental disorder marked by delusions (false beliefs), hallucinations, disrupted thinking, and loss of contact with reality. It is also used for the treatment of manic and depressive episodes associated with bipolar disorder.

Quetiapine fumarate belongs to one of the newer classes of antipsychotic medications. Researchers believe that it works by diminishing the action of dopamine and serotonin, two of the brain's chief chemical messengers.

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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