

Qutyl[®]

[Quetiapine]

Tablet

COMPOSITION:

Qutyl Tablet 25 mg:

Each film coated tablet contains:
Quetiapine Fumarate equivalent to
Quetiapine 25 mg.

Product Specs.: CCL Pharmaceuticals

Qutyl Tablet 100 mg:

Each film coated tablet contains:
Quetiapine Fumarate equivalent to
Quetiapine 100 mg.

Product Specs.: CCL Pharmaceuticals

Qutyl Tablet 200 mg:

Each film coated tablet contains:
Quetiapine Fumarate equivalent to
Quetiapine 200 mg.

Product Specs.: CCL Pharmaceuticals

DESCRIPTION:

Quetiapine Fumarate is an atypical psychotropic agent belonging to a chemical class, the dibenzothiazepine derivatives. Quetiapine is an antagonist at multiple neurotransmitter receptors in the brain: serotonin 5HT1A and 5HT2, dopamine D1 and D2, histamine H1, and adrenergic α_1 and α_2 receptors. Quetiapine has no appreciable affinity at cholinergic muscarinic and benzodiazepine receptors. The mechanism of action of Quetiapine is unknown. However, it has been proposed that this drug's efficacy in schizophrenia is mediated through a combination of dopamine D2 and serotonin 5HT2 antagonism. Quetiapine's antagonism of histamine H1 receptors may explain the somnolence and that of adrenergic α_1 receptors may explain the orthostatic hypotension observed with this drug. Elimination of Quetiapine is mainly via hepatic metabolism with a mean terminal half-life of about 6 hours. Steady-state concentrations are expected to be achieved within two days of dosing. Quetiapine is unlikely to interfere with the metabolism of drugs metabolized by cytochrome P450 enzymes. Quetiapine is rapidly absorbed after oral administration, reaching peak plasma concentrations in 1.5 hours. The tablet formulation is 100% bioavailable relative to solution. The bioavailability of Quetiapine is marginally affected by administration with food, with Cmax and AUC values increased by 25% and 15%, respectively. It is 83% bound to plasma proteins at therapeutic concentrations. Following a single oral dose less than 1% of the administered dose is excreted as unchanged drug. Approximately 73% and 20% of the doses were recovered in the urine and feces, respectively. Quetiapine is extensively metabolized by the liver.

INDICATIONS AND USES:

Bipolar Mania - Quetiapine is indicated for the treatment of acute manic episodes associated with bipolar I disorder, as either monotherapy or adjunct therapy to lithium or divalproex.

Schizophrenia:

Quetiapine is indicated for the treatment of schizophrenia. Physician who elects to use Quetiapine for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

CONTRAINDICATIONS:

Quetiapine is contraindicated in individuals with a known hypersensitivity to this medication or any of its ingredients.

DRUG INTERACTIONS:

Phenytoin and thioridazine markedly decrease the amount of Quetiapine that is absorbed from the intestine and thereby reduces its effectiveness. Therefore, patients taking phenytoin or thioridazine may require higher doses of Quetiapine.

Quetiapine can cause hypotension and therefore increase the blood pressure lowering effects of antihypertensive drugs.

Quetiapine can increase the sedating effects of other drugs that sedate.

Such drugs include narcotic pain relievers [for example, oxycodone and acetaminophen], barbiturates, sedatives such as alprazolam and clonazepam, ethanol, and blood pressure drugs that can cause orthostatic hypotension, such as prazosin and terazosin.

Quetiapine is eliminated from the body by an enzyme in the liver called cytochrome P450 3A. There is a concern that drugs that strongly interfere with the enzyme, for example, ketoconazole, itraconazole, fluconazole, and erythromycin, clarithromycin, nefazodone, verapamil, or diltiazem may cause elevated and toxic levels of Quetiapine.

DOSAGE AND ADMINISTRATION:

Bipolar mania:

As monotherapy or as adjunct therapy with other anti-psychotic drugs.

Days dosage:

1st 50 mg Twice daily
2nd 100 mg Twice daily

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3rd 150 mg Twice daily
4th 200 mg Twice daily
5th 300 mg Twice daily
6th 400 mg Twice daily

Data indicates that the majority of patients responded between 400 to 800 mg/day. The safety of doses above 800 mg/day has not been evaluated in clinical trials.

Schizophrenia:

Usual dose:

Quetiapine should generally be administered with an initial dose of 25 mg bid, with increments of 25-50 mg bid or tid on the second and third day, as tolerated, to a target dose range of 300 to 400 mg daily by the fourth day, given bid or tid. Further dosage adjustments, if indicated, should generally occur at intervals of not less than 2 days, as steady-state for Quetiapine would not be achieved for approximately 1-2 days in the typical patient. When dosage adjustments are necessary, dose increments/decrements of 25-50 mg bid are recommended. Most efficacy data with Quetiapine were obtained using tid regimens, but in one controlled trial 225 mg bid was also effective.

PRECAUTIONS:

Neuroleptic malignant syndrome, tardive dyskinesia. Hypotension and syncope, especially during the initial dose titration period. Conduct eye examinations prior to or shortly after starting Quetiapine and at 6-month intervals thereafter; discontinue the drug if clinically significant changes are observed. History of seizures. Hypothyroidism. Hyperprolactinemia. Antiemetic effect. Suicide. Use with great caution in moderate or severe hepatic impairments. Renal impairment, cardiovascular disease, Disruption of body temperature regulation, Hyperglycemia. Lactation (avoid breast-feeding).

Pregnancy & lactation:

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women and Quetiapine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing mothers: It is recommended that women receiving Quetiapine should not breast feed.

Pediatric use: The safety and effectiveness of Quetiapine in pediatric patients less than 18 years have not been established.

SIDE EFFECTS:

Somnolence, dizziness, dry mouth, constipation, dyspepsia, postural hypotension, elevated ALT (SGPT) levels, weight gain.

INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

Qutyl Tablet 25 mg : Pack of 1 x 10 tablets.
Qutyl Tablet 100 mg : Pack of 1 x 10 tablets.
Qutyl Tablet 200 mg : Pack of 1 x 10 tablets.

ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی، دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:



Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
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