

Qpine™

Quetiapine Fumarate INN



Presentation

Qpine 25: Each tablet contains Quetiapine Fumarate INN equivalent to Quetiapine 25mg.

Qpine 100: Each tablet contains Quetiapine Fumarate INN equivalent to Quetiapine 100mg.

Qpine 200: Each tablet contains Quetiapine Fumarate INN equivalent to Quetiapine 200mg.

Mode of action

Quetiapine is an atypical psychotropic agent belonging to a chemical class, the dibenzothiazepine derivatives.

Quetiapine is an antagonist at multiple neurotransmitter receptors in the brain, such as serotonin 5-HT_{1A} and 5-HT₂, dopamine D₁ and D₂, histamine H₁, and adrenergic 1 and 2 receptors. Quetiapine has no appreciable affinity at cholinergic muscarinic and benzodiazepine receptors. The actual 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 5-HT₂ antagonism. Quetiapine's antagonism of histamine H₁ receptors may explain the somnolence and that of adrenergic₁ receptors may explain the orthostatic hypotension observed with this drug.

Indication

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.

Contra-indications

Known hypersensitivity to this medication or any of its ingredients.

Side-Effect

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

Precautions

Neuroleptic malignant syndrome, tardive dyskinesia. Hypotension and syncope, specially 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 lens changes are observed. History of seizures, Hypothyroidism, Hyperprolactinemia, Antiemetic effect and Suicide. Use with great caution in moderate or severe hepatic impairments. Renal impairment, Cardiovascular disease, Disruption of body temperature regulation, Hyperglycemia and Lactation (avoid breast-feeding).

Pregnancy and Lactation

Quetiapine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing mothers receiving Quetiapine should not breast feed.

Dose and Administration

Bipolar mania: As monotherapy or as adjunct therapy with other anti-psychotic drugs: 1st day- 50mg twice daily; 2nd day- 100mg twice daily; 3rd day- 150mg twice daily; 4th day- 200mg twice daily; 5th day- 300mg twice daily; 6th day- 400mg twice daily. Data indicates that the majority of patients responded between 400mg to 800mg/day. The safety of does above 800mg/day has not been evaluated in clinical trials.

Schizophrenia: Usual dose: Quetiaphine should generally be administered with an initial dose of 25mg twice daily, with increments of 25-50mg twice daily or thrice daily on the second and third day, as tolerated, to a target dose range of 300mg to 400mg daily by the 4th day, given twice daily or thrice daily. 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 25-50mg twice daily are recommended. Most efficacy data with Quetiapine were obtained using thrice daily regimens, but in one controlled trial 225mg twice daily was also effective. Physician who elects to use Quetiapine for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

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

Drug Interactions

May enhance the effects of other centrally acting drugs, certain antihypertensive agents; may antagonize the effects of dopamine agonists and levodopa. Increased clearance of quetiapine by phenytoin, barbiturates, rifampicin, carbamazepine. Increased concentrations of quetiapine with azole antifungals and macrolide antibiotics.

Storage Condition

Store in a cool and dry place away from light.

Commercial Pack

Qpine 25mg: 10 X 10's Tablet in alu-pvc blister packs.

Qpine 100mg: 3 X 10's Tablet in alu-pvc blister packs.

Qpine 200mg: 3 X 10's Tablet in alu-pvc blister packs.


Manufactured by:



Synovia Pharma PLC., Station Road, Tongi, Gazipur.

A Subsidiary of BEXIMCO PHARMACEUTICALS LTD. 517185/2

Direction Slip artwork legend

Product Name	:	Qpine
Code number	:	517185/2
CDCS Version	:	02
Dimension	:	L 17.3 x W 2.75 inches
Min. size of text	:	8 pt
Used Colors	:	Black C  Pantone 186 C 