

Seroprex™

Quetiapine

Composition

Seroprex™ 25: Each film-coated tablet contains Quetiapine Fumarate USP equivalent to Quetiapine 25 mg.

Seroprex™ 100: Each film-coated tablet contains Quetiapine Fumarate USP equivalent to Quetiapine 100 mg.

Pharmacology

Seroprex™ (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 5HT_{1A} 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.

Indications and Uses

Seroprex™ (Quetiapine Fumarate) is indicated in the treatment of:

- Bipolar Disorder
- Schizophrenia

Dosage and Administration

Seroprex™ (Quetiapine Fumarate) can be taken with or without food as per following:

Indication	Initial dose and titration	Recommended dose
Schizophrenia-Adults	Day 1: 300 mg/day Dose increments can be made at intervals as short as 1 day and in increments of up to 300 mg/day	400-800 mg/day
Schizophrenia-Adolescents (13 to 17 years)	Day 1: 50 mg/day; Day 2: 100 mg/day; Day 3: 200 mg/day; Day 4: 300 mg/day; Day 5: 400 mg/day	400-800 mg/day
Schizophrenia Maintenance - Monotherapy - adults	N/A	400-800 mg/day
Bipolar Mania - Acute monotherapy, Children or Adolescents (13 to 17 years)	Day 1: 50 mg/day; Day 2: 100 mg/day; Day 3: 200 mg/day; Day 4: 300 mg/day; Day 5: 400 mg/day	400-600 mg/day
Bipolar Mania or mixed-Acute monotherapy or as an adjunct to Lithium or Divalproex in adults	Day 1: 300 mg/day; Day 2: 600 mg/day; Day 3: 400-800 mg/day	400-800 mg/day
Depressive Episodes Associated with Bipolar Disorder	Day 1: 50 mg/day; Day 2: 100 mg/day; Day 3: 200 mg/day; Day 4: 300 mg/day	300 mg/day
Major Depressive Disorder, Adjunctive Therapy with Antidepressants	Day 1 & 2: 50 mg/day 3 & 4: 150 mg/day	150-300 mg/day

Contraindications

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

Side-effects

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

Warning & 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 lens 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).

Use in special population

Use in Pregnancy and 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 13 years with schizophrenia, less than 10 years with bipolar mania and less than 18 years for bipolar depression have not been established.

Hepatic Impairment: Lower starting dose (50 mg/day) and slower titration may be needed.

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, rifampin, carbamazepine. Increased concentrations of Quetiapine with azole antifungals and macrolide antibiotics.

Storage

Protect from light, store below 30° C. Keep the medicine out of the reach of children.

How Supplied

Seroprex™ 25: Each box contains 30 tablets in Blister pack.

Seroprex™ 100: Each box contains 30 tablets in Blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH