Seropin®

Quetiapine Fumarate USP film coated tablet

DESCRIPTION

Seropin® is a preparation of Quetiapine. Quetiapine is a psychotropic agent belonging to a chemical class, the dibenzothiazepine derivatives. The mechanism of action of Quetiapine, as with other drugs having efficacy in the treatment of schizophrenia and bipolar disorder, is unknown. However, it has been proposed that the efficacy of Quetiapine in schizophrenia and its mood stabilizing properties in bipolar depression and mania are mediated through a combination of dopamine type 2 (D2) and serotonin type 2 (5HT2) antagonism. Antagonism at receptors other than dopamine and 5HT2 with similar receptor affinities may explain some of the other effects of Quetiapine. Quetiapine antagonism of histamine H_1 receptors may explain the somnolence observed with this drug.

INDICATIONS

- Treatment of schizophrenia
- Acute treatment of depressive episodes associated with bipolar disorder

DOSAGE AND ADMINISTRATION

Indication	Dosing Instructions	Recommended Dose / Dose Range
Schizophrenia-Adults	Day 1: 25 mg twice daily. Increase in increments of 25 mg-50 mg divided two or three times on Days 2 and 3 to range of 300-400 mg by Day 4. Further adjustments can be made in increments of 25-50 mg twice a day, in intervals of not less than 2 days.	150-750 mg/day
Schizophrenia-Adolescents (13-17 years)	Day 1: 25 mg twice daily. Day 2: Twice daily dosing totaling 100 mg. Day 3: Twice daily dosing totaling 200 mg. Day 4: Twice daily dosing totaling 300 mg. Day 5: Twice daily dosing totaling 400 mg. Further adjustments should be in increments no greater than 100 mg/day within the recommended dose range of 400-800 mg/day. Based on response and tolerability, may be administered three times daily.	400-800 mg/day
Bipolar Mania-Adults Monotherapy or as an adjunct to lithium or divalproex	Day 1: Twice daily dosing totaling 100 mg. Day 2: Twice daily dosing totaling 200 mg. Day 3: Twice daily dosing totaling 300 mg. Day 4: Twice daily dosing totaling 400 mg. Further dosage adjustments up to 800 mg/day by Day 6 should be in increments of no greater than 200 mg/day.	400-800 mg/day
Bipolar Mania-Children and Adolescents (10 to 17 years), Monotherapy	Day 1: 25 mg twice daily. Day 2: Twice daily dosing totaling 100 mg. Day 3: Twice daily dosing totaling 200 mg. Day 4: Twice daily dosing totaling 300 mg. Day 5: Twice daily dosing totaling 400 mg. Further adjustments should be in increments no greater than 100 mg/day within the recommended dose range of 400-600 mg/day. Based on response and tolerability, may be administered three times daily.	400-600 mg/day
Bipolar Depression-Adults	Administer once daily at bedtime. Day 1: 50 mg Day 2: 100 mg Day 3: 200 mg Day 4: 300 mg	300 mg/day
Bipolar I Disorder Maintenance Therapy-Adults	Administer twice daily totaling 400-800 mg/day as adjunct to lithium or divalproex. Generally, in the maintenance phase, patients continued on the same dose on which they were stabilized.	

Note: After initial dosing, adjustments can be made upwards or downwards, if necessary, within the dose range depending upon the clinical response and tolerance of the patient.

CONTRAINDICATIONS

Quetiapine tablet is contraindicated in individuals with a known hypersensitivity to Quetiapine Fumarate.

SIDE EFFECTS

1. Risk of death in the elderly with dementia
2. Risk of suicidal thoughts or actions
3. High blood suger (Hyperglycemia)
4. High fat levels in blood
5. Weight gain

PRECAUTIONS AND WARNING

Atypical anti-psychotic drugs, including Quetiapine, are associated with an increased risk of death; causes of death are variable. Increased the risk of suicidal thinking and behavior in children, adolescents and young adults taking antidepressants for major depressive disorder and other psychiatric disorders. Ketoacidosis, hyperosmolar coma and death have been reported in patients treated with atypical antipsychotics, including Quetiapine. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. When starting treatment, patients with diabetes or risk factors for diabetes should undergo blood glucose testing before and during treatment.

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

PHARMACEUTICAL PRECAUTION

Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Seropin® 25 Tablet: Box containing 5 strips of 10 tablets each. Each film coated tablet contains Quetiapine Fumarate USP equivalent to Quetiapine 25 mg.

Seropin® 100 Tablet: Box containing 3 strips of 10 tablets each. Each film coated tablet contains Quetiapine Fumarate USP equivalent to Quetiapine 100 mg.

SK+F

Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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