

Only for the use of Medical Professionals

Qmax[®]
Quetiapine

Description

Qmax[®] is a preparation of Quetiapine Fumarate which is an antipsychotic agent. Quetiapine and the active human plasma metabolite (norquetiapine) exhibit affinity for brain serotonin (5HT₂) and dopamine D₁ and D₂ receptors. This combination of receptor antagonism shows higher selectivity for 5HT₂ relative to dopamine D₂ receptors which is believed to contribute to the clinical antipsychotic properties and low extra-pyramidal side effect (EPS) compared to typical antipsychotics. Quetiapine is well absorbed and extensively metabolized after oral administration. The elimination half-lives of Quetiapine and norquetiapine are approximately 7 and 12 hours respectively.

Indications

Qmax[®] is indicated for the treatment of-

- Schizophrenia.
- Bipolar disorder including:
 - Manic episodes associated with bipolar disorder.
 - Major depressive episodes in bipolar disorder.
 - Preventing recurrence in bipolar disorder in patients whose manic, mixed or depressive episode has responded to Quetiapine treatment.

Dosage and administration

For Schizophrenia:

Adult over 18 years: 25 mg twice daily on day 1, 50 mg twice daily on day 2, 100 mg twice daily on day 3, 150 mg twice daily on day 4, then adjusted according to response, usual range 300-450 mg daily in 2 divided doses; max. 750 mg daily.

Elderly: initially 25 mg daily as a single dose, increased in steps of 25-50 mg daily in 2 divided doses.

Children of 12-18 years: Not recommended.

For mania in bipolar disorder:

Adult over 18 years: 50 mg twice daily on day 1, 100 mg twice daily on day 2, 150 mg twice daily on day 3, 200 mg twice daily on day 4, then adjusted according to response in steps of up to 200 mg daily to max. 800 mg daily; usual range is 400-800 mg daily in 2 divided doses.

Elderly: initially 25 mg daily as a single dose, increased in steps of 25-50 mg daily in 2 divided doses.

Children of 12-18 years: Not recommended.

Depression in bipolar disorder:

Adult over 18 years: 50 mg once daily (at bedtime) on day 1, 100 mg once daily on day 2, 200 mg once daily on day 3, 300 mg once daily on day 4; adjust according to response, usual dose 300 mg once daily, max. 600 mg daily.

Prevention of mania and depression in bipolar disorder:

Adult over 18 years: Continue at the dose effective for treatment of bipolar disorder and adjust to lowest effective dose; usual range is 300-800 mg in 2 divided doses.

Hepatic impairment:

Starting dose is initially 25 mg daily, increased daily in steps of 25-50 mg.

Use in pregnancy and lactation

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.

Side Effects

Common side effects of Quetiapine are dry mouth, constipation, dyspepsia, tachycardia, hypertension, elevated plasma-triglyceride and cholesterol concentration, peripheral edema, drowsiness, headache, irritability, asthenia, leucopenia, neutropenia, blurred vision, rhinitis. Less common side effects are dysphagia, seizures, restless legs syndrome, hyponatraemia, eosinophilia, jaundice and priapism.

Precautions

Caution should be exercised when treating patients with cerebrovascular disease, patients at risk of aspiration pneumonia, treatment of depression in patients under 25 years (increased risk of suicide) or a history of seizures, hepatic impairment. If signs and symptoms of tardive dyskinesia, neuroleptic malignant syndrome, hypotension and syncope appear, dose reduction or discontinuation of Quetiapine should be considered.

Contraindications

Quetiapine is contraindicated in patients with known hypersensitivity to active ingredient or any component of the product.

Drug interaction

Increased clearance of Quetiapine by phenytoin, barbiturates, thioridazine, carbamazepine. Increased concentrations of Quetiapine when concomitantly administered with cytochrome P450 3A4 inhibitors such as HIV-protease inhibitors, azole-antifungal agents, erythromycin, clarithromycin and nefazodone.

Quetiapine may enhance the effects of other centrally acting drugs, certain antihypertensive agents; may antagonize the effects of dopamine agonists and levodopa.

Overdose

In case of acute overdosage, establish and maintain an airway and ensure adequate oxygenation and ventilation. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring. Gastric lavage and administration of activated charcoal together with a laxative should be considered. Close medical supervision and monitoring should be continued until the patient recovers.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light. Keep away from the reach of children.

Presentation

Qmax[®] 25 tablet: Each coated tablet contains Quetiapine 25 mg as Fumarate INN.

Qmax[®] 100 tablet: Each coated tablet contains Quetiapine 100 mg as Fumarate INN.

Package quantities

Qmax[®] 25 tablet: Carton of 50 tablets in blister pack.

Qmax[®] 100 tablet: Carton of 50 tablets in blister pack.

® Registered Trade Mark



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Narayanganj, Bangladesh