Tiapine

Quetiapine Tablet

Presentation
TIAPINE 100 Tablet: Each film coated tablet contains Quetiapine Fumarate INN equivalent to Quetiapine 100 mg.
TIAPINE 25 Tablet: Each film coated tablet contains Quetiapine Fumarate INN equivalent to Quetiapine 25 mg.

Pharmacodynamic properties
Quetiapine Fumarate is an atypical antipsychotic agent. Quetiapine Fumarate is an antagonist at multiple neurotransmitter receptors in the brain: serotonin $5HT_{1A}$ and $5HT_2$, dopamine D_1 and D_2, histamine H_1 and adrenergic α_1 and α_2 receptors. Quetiapine Fumarate has no appreciable affinity at cholinergic muscarinic and benzodiazepine receptors. The efficacy of Quetiapine Fumarate in schizophrenia is mediated through a combination of dopamine (D_2) and serotonin ($5HT_2$) receptor antagonism. Quetiapine's antagonism of histamine H_1 receptors causes somnolence and antagonism of adrenergic α1 receptors causes orthostatic hypotension.

Pharmacokinetic properties
Quetiapine Fumarate 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 Fumarate is marginally affected by administration with food. Quetiapine Fumarate is widely distributed throughout the body. It is 83% bound to plasma proteins at therapeutic concentrations. Approximately 73% and 20% of the dose was recovered in the urine and faces, respectively. Elimination of Quetiapine Fumarate is mainly via hepatic metabolism with a mean terminal half-life of about 6 hours within the proposed clinical dose range. Steady-state concentrations are expected to be achieved within two days of dosing.

Indications

- ◊ Schizophrenia
- ◊ Acute manic episodes associated with bipolar I disorder, as monotherapy or adjunct therapy to mood stabilizers

Dosage & Administration
Quetiapine should be administered twice daily, with or without food.
Adults

For the treatment of schizophrenia:	
Day	**Total daily dose**
1st	50 mg in two divided doses
2nd	100 mg in two divided doses
3rd	200 mg in two divided doses
4th	300 mg in two divided doses

From day 4 onwards, the dose should be titrated to the usual effective dose range of 300 to 450 mg/day. Depending on the clinical response and tolerability of the individual patient, the dose may be adjusted within the range of 150 to 750 mg/day.

For the treatment of manic episodes associated with bipolar disorder: (As monotherapy or as adjunct therapy to mood stabilizers)	
Day	**Total daily dose**
1st	100 mg in two divided doses
2nd	200 mg in two divided doses
3rd	300 mg in two divided doses
4th	400 mg in two divided doses

Further dosage adjustments up to 800 mg per day by day 6 should be in increments of no greater than 200 mg per day. The dose may be adjusted depending on clinical response and tolerability of the individual patient, within the range of 200 to 800 mg per day. The usual effective dose is in the range of 400 to 800 mg per day.
Elderly
As with other antipsychotics, Quetiapine should be used with caution in the elderly, especially during the initial dosing period. Elderly patients should be started on Quetiapine 25 mg/day. The dose should be increased daily, in increments of 25 to 50 mg to an effective dose, which is likely to be lower than that in younger patients.
Children and adolescents
The safety and efficacy of Quetiapine have not been evaluated in children and adolescents.

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

Side Effects
The very commonly reported side effects with Quetiapine is dizziness; commonly reported side effects are somnolence, leucopenia, tachycardia, dry mouth, mild asthenia, constipation, orthostatic hypotension, dyspepsia, syncope, peripheral edema, weight gain, elevation in serum transaminases and rhinitis.

Precautions
Quetiapine should be used with caution in patients with cardiovascular disease and cerebrovascular disease, seizures, tardive dyskinesia and neuroleptic malignant syndrome. In such an event dose reduction or discontinuation of Quetiapine should be considered.
Acute withdrawal reactions: Acute withdrawal symptoms including nausea, vomiting and insomnia have very rarely been described after abrupt cessation of high doses of antipsychotic drugs. Recurrence of psychotic symptoms may also occur and the appearances of involuntary movement disorders (such as akathisia, dystonia and dyskinesia) have been reported. Therefore, gradual withdrawal is advisable.

Drug Interactions
Quetiapine should be used with caution in combination with other centrally acting drugs and alcohol. Co-administration of Quetiapine with phenytoin, thioridazine and carbamazepine increases clearance of Quetiapine. Co-administration with potent CYP3A4 inhibitors such as azole antifungals and macrolide antibiotics increases plasma concentration of Quetiapine. Quetiapine may antagonize the effects of levodopa and dopamine agonists.

Use in Pregnancy and Lactation
Pregnancy category C. The safety and efficacy of Quetiapine during human pregnancy have not been established. Therefore, Quetiapine should only be used during pregnancy if the benefits justify the potential risks. Women receiving Quetiapine should not breast feed.

Overdose
In human, experience with Quetiapine Fumarate in acute overdosage was limited with estimated doses ranging from 1200 mg to 9600 mg and no fatalities were reported. In general, reported signs and symptoms were drowsiness and sedation, tachycardia and hypotension. In case of acute overdosage, ensure adequate oxygenation and ventilation. Close medical supervision with cardiovascular monitoring should continue until the patient recovers.

Commercial Pack
TIAPINE 100 Tablet: Each box contains 3 blister packs of 10 tablets.
TIAPINE 25Tablet: Each box contains 5 blister packs of 10 tablets.

Manufactured by :
general **GENERAL Pharmaceuticals Ltd.**
Gazipur, Bangladesh
GENERAL Pharmaceuticals Ltd. ISO 9001:2008 Certified Company