QTP™

Quetiapine

COMPOSITION

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

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

QTP™ 200 XR: Each extended release tablet contains Quetiapine Fumarate USP equivalent to Quetiapine 200 mg.

PHARMACOLOGY

QTP™ (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 $5HT_2$, dopamine D_1 and D_2, histamine H_1, 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 D_2 and serotonin $5HT_2$ antagonism. Quetiapine's antagonism of histamine H_1 receptors may explain the somnolence and that of adrenergic α_1 receptors may explain the orthostatic hypotension observed with this drug.

INDICATIONS AND USES

QTP™ (Quetiapine Fumarate) is indicated in the treatment of Bipolar Disorder & Schizophrenia.

DOSAGE AND ADMINISTRATION

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

Indication	Initial Dose	Recommended Dose	Maximum Dose
Schizophrenia-Adults	25 mg twice daily	150-750 mg/day	750 mg/day
Schizophrenia-Adolescents (13 to 17 years)	25 mg twice daily	400-800 mg/day	800 mg/day
Bipolar Mania - Adults Monotherapy or as an adjunct to lithium or divalproex	50 mg twice daily	400-800 mg/day	800 mg/day
Bipolar Mania - Children and Adolescents (10-17 years), Monotherapy	25 mg twice daily	400-600 mg/day	600 mg/day
Bipolar Depression - Adults	50 mg once daily at bedtime	300 mg/day	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 uetiapine and at 6 month intervals thereafter; discontinue the drug if clinically significant less 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 reast-feeding).

USE IN SPECIAL POPULATION

Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure.

Geriatric Use: Consider a lower starting dose (50 mg/day), slower titration and careful monitoring during the initial dosing period in the elderly.

Hepatic Impairment: Lower starting dose (25 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 and moisture store below 30° C. Keep the medicine out of the reach of children. Use only on the advice of a registered physician.

HOW SUPPLIED

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

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

QTP™ 200 XR: Each box contains 20 tablets in Blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS PLC.
BANGLADESH