

Ariquet

Quetiapine Fumarate USP

COMPOSITION

Ariquet 25: Each film coated tablet contains Quetiapine Fumarate USP equivalent to Quetiapine 25 mg.

Ariquet 50 ER: Each extended-release film coated tablet contains Quetiapine Fumarate USP equivalent to Quetiapine 50 mg.

Ariquet 100: Each film coated tablet contains Quetiapine Fumarate USP equivalent to Quetiapine 100 mg.

PHARMACOLOGY

Quetiapine Fumarate, an atypical psychotropic drug, is a member of the dibenzothiazepine family. Its effectiveness for schizophrenia is likely due to its ability to block dopamine D₂ and serotonin 5HT₂ receptors in the brain. The drug also acts as an antagonist at several other receptors, including serotonin 5HT_{1A}, dopamine D₁, histamine H₁, adrenergic α₁ and α₂ receptors. Quetiapine's antagonism of histamine H₁ receptors may cause somnolence (sleepiness), and its antagonism of adrenergic α₁ receptors may lead to orthostatic hypotension (a drop in blood pressure when standing up). The drug does not significantly bind to cholinergic muscarinic or benzodiazepine receptors.

INDICATIONS

Quetiapine Fumarate is indicated for the treatment of Bipolar Disorder & Schizophrenia.

DOSAGE & ADMINISTRATION

Quetiapine Fumarate can be taken with or without food as per following:

Indication	Initial Dose	Recommended Dose/ Dose Range
Schizophrenia-Adults	25 mg twice daily	150-750 mg/day
Schizophrenia-Adolescents (13 to 17 years)	25 mg twice daily	400-800 mg/day
Bipolar Mania - Adults (Monotherapy or as an adjunct to lithium or divalproex)	50 mg twice daily	400-800 mg/day
Bipolar Mania - Children and Adolescents (10-17 years), Monotherapy	25 mg twice daily	400-600 mg/day
Bipolar Depression - Adults	50 mg once daily (at bedtime)	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.	

CONTRAINDICATION

Use of quetiapine is not recommended for patients who have shown a hypersensitivity to the drug or its ingredients.

WARNING & PRECAUTION

If signs and symptoms of Neuroleptic malignant syndrome, tardive dyskinesia, low blood pressure, fainting (especially during initial dose titration period) appear, dose reduction or discontinuation of Quetiapine should be considered. Perform eye exams before starting and every 6 months; stop if significant lens changes occur. Use cautiously in patients with seizures, thyroid disorders, high prolactin, liver/kidney disease, heart disease, blood sugar issues, or temperature regulation problems.

SIDE EFFECT

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

USE IN SPECIAL POPULATION

Pregnancy: Quetiapine should be used only if the potential benefit justifies the potential risk.

Lactation: It is recommended that women receiving Quetiapine should not breast feed.

In children: Safety and effectiveness have only been established for schizophrenia in adolescent patients 13 to 17 years of age and in bipolar mania in children and adolescent patients 10 to 17 years of age.

In geriatric patients: A lower starting dose (50 mg/day), slower titration, and careful monitoring during the initial dosing period should be considered.

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

DRUG INTERACTION

Caution should be exercised when Quetiapine is used concomitantly with medicines known to cause electrolyte imbalance or to increase QT interval. Co-administration of Quetiapine and thioridazine or carbamazepine caused increases in the clearance of Quetiapine. Co-administration of Quetiapine with another microsomal enzyme inducer, phenytoin, also caused increases in the clearance of Quetiapine.

OVERDOSE

There is no specific antidote to Quetiapine. In cases of severe intoxication, the possibility of multiple drug involvement should be considered, and intensive care procedures are recommended, including establishing and maintaining a patent airway, ensuring adequate oxygenation and ventilation, and monitoring and support of the cardiovascular system and close medical supervision and monitoring should continue until the patient recovers.

STORAGE

Do not store above 30°C. Keep away from light and out of the reach of children.

PACKING

Ariquet 25: Each box contains 50 tablets in alu-alu blister pack.

Ariquet 50 ER: Each box contains 50 tablets in alu-alu blister pack.

Ariquet 100: Each box contains 30 tablets in alu-alu blister pack.

Manufactured by:



ARISTOPHARMA LTD.

Shampur-Kadamtali I/A, Dhaka-Bangladesh