

Ariprex™

Aripiprazole USP

Composition

Ariprex™ 2 Tablet: Each tablet contains Aripiprazole USP 02 mg.

Ariprex™ 10 Tablet: Each tablet contains Aripiprazole USP 10 mg.

Ariprex™ 15 Tablet: Each tablet contains Aripiprazole USP 15 mg.

Ariprex™ Oral Solution: Each 5 ml oral solution contains Aripiprazole USP 5 mg.

Pharmacology

Ariprex™ is an atypical antipsychotic and it has been proposed that the efficacy of **Ariprex™** is mediated through a combination of partial agonist activity at Dopamine D₂ and Serotonin 5-HT_{1A} receptors and antagonist activity at Serotonin 5-HT_{2A} receptors. This is associated with improvement of schizophrenia, bipolar disorder, major depressive disorder, irritability associated with autistic disorder, and agitation associated with schizophrenia or bipolar disorder.

Uses

Schizophrenia, bipolar disorder, adjunctive treatment of major depressive disorder, irritability associated with autistic disorder, agitation associated with schizophrenia or bipolar mania.

Contraindication

Known hypersensitivity to Aripiprazole.

Drug interaction

Caution should be exercised when Aripiprazole is taken in combination with other centrally acting drugs and alcohol. Carbamazepine could cause an increase in Aripiprazole clearance and lower blood levels. Ketoconazole, quinidine, fluoxetine or paroxetine can inhibit Aripiprazole elimination and cause increased blood levels.

Use in pregnancy and lactation

Pregnancy: Pregnancy category C. It should be avoided during pregnancy.

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

Storage

Protect from light and moisture, store below 30° C. Keep out of the reach of children.

Dosage & administration

Indications	Initial Dose	Recommended Dose	Maximum Dose
Schizophrenia – adults	10-15 mg/day	10-15 mg/day	30 mg/day
Schizophrenia – adolescents (ages 13-17 years)	2 mg/day	10 mg/day	30 mg/day
Bipolar mania – adults: monotherapy	15 mg/day	15 mg/day	30 mg/day
Bipolar mania – adults: adjunct to lithium or valproate	10-15 mg/day	15 mg/day	30 mg/day
Bipolar mania – pediatric patients (ages 10-17 years): monotherapy or as an adjunct to lithium or valproate	2 mg/day	10 mg/day	30 mg/day
As an adjunct to antidepressants for the treatment of major depressive disorder – adults	2-5 mg/day	5-10 mg/day	15 mg/day
Irritability associated with autistic disorder-pediatric patients (ages 6-17 years)	2 mg/day	5-10 mg/day	15 mg/day

• Oral formulations: Administer once daily without regard to meals.

• IM injection: Wait at least 2 hours between doses. Maximum daily dose 30 mg.

Adverse effects

Vomiting, nausea, akathisia, extrapyramidal disorder, somnolence, sedation, dizziness, insomnia, tremor, restlessness, fatigue, blurred vision, salivary hypersecretion, constipation, pyrexia, drooling, decreased appetite.

Special warnings and precautions for use

Elderly Patients with Dementia-Related Psychosis: Increased incidence of cerebrovascular adverse events (eg, stroke, transient ischemic attack, including fatalities).

Suicidality & antidepressants: Increased risk of suicidality in children, adolescents, young and adults with major depressive disorder.

Tardive dyskinesia: Discontinue if clinically appropriate.

Metabolic changes: Atypical antipsychotic drugs have been associated with metabolic changes that include hyperglycemia/diabetes mellitus, dyslipidemia, and body weight gain.

Orthostatic hypotension: Use with caution in patients with known cardiovascular or cerebrovascular disease.

Seizures/Convulsions: Use cautiously in patients with a history of seizures.

Use caution when operating machinery.

How supplied

Ariprex™ 2 Tablet: Box containing 30 tablets in blister pack.

Ariprex™ 10 Tablet: Box containing 30 tablets in blister pack.

Ariprex™ 15 Tablet: Box containing 30 tablets in blister pack.

Ariprex™ Oral Solution: Each PET bottle contains 50 ml oral solution with measuring cup & dropper.

Manufactured by:



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH