

2D Data Matrix to be printed with serial number on each leaflet. The number should not be repeated

Note: Position of the pharma code and product name will change as per the folding machine feasibility

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use **ARIPRAZOLE TABLETS** safely and effectively. See full prescribing information for **ARIPRAZOLE TABLETS**.

ARIPRAZOLE TABLETS, for oral use
U.S. Approval: 2002

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS AND SUICIDAL THOUGHTS AND BEHAVIORS WITH ANTIDEPRESSANT DRUGS

See full prescribing information for complete boxed warning.

- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. **Aripiprazole tablets are not approved for the treatment of patients with dementia-related psychosis.** (5.1)
- Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants. **Monitor for worsening and emergence of suicidal thoughts and behaviors.** (5.3)

RECENT MAJOR CHANGES

Warnings and Precautions (1) 1/2025
Orthostatic Hypotension (5.8) 1/2025
Seizures/Convulsions (5.11) 1/2025
Potential for Cognitive and Motor Impairment (5.12) 1/2025

INDICATIONS AND USAGE

Aripiprazole tablets are an atypical antipsychotic. Aripiprazole tablets are indicated for:

- Schizophrenia (1.4)
- Irritability Associated with Autistic Disorder (14.4)
- Treatment of Tourette's Disorder (14.5)

DOSEAGE AND ADMINISTRATION

- Administer once daily without regard to meals (2)

	Initial Dose	Recommended Dose	Maximum Dose
Schizophrenia – adults (2.1)	10 to 15 mg/day	10 to 15 mg/day	30 mg/day
Schizophrenia – adolescents (2.1)	2 mg/day	10 mg/day	30 mg/day
Irritability associated with autistic disorder – pediatric patients (2.4)	2 mg/day	5 to 10 mg/day	15 mg/day

Tourette's Disorder – (2.5)
Patients < 50 kg 2 mg/day 5 mg/day 10 mg/day
Patients ≥ 50 kg 2 mg/day 10 mg/day 20 mg/day

Known CYP2D6 poor metabolizers: Half of the usual dose (2.6)

DOSEAGE FORMS AND STRENGTHS

Tablets: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg

CONTRAINDICATIONS

- Known hypersensitivity to aripiprazole tablets (4)

WARNINGS AND PRECAUTIONS

Cardiovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis: Increased incidence of cardiovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities) (5.1, 5.2)

Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring (5.4)

Tardive Dyskinesia: Discontinue if clinically apparent (5.9)

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include hyperglycemia/diabetes mellitus, weight gain, and increased risk of diabetes (5.6)

Hyperglycemia/Diabetes Mellitus: Monitor glucose regularly in patients with and at risk for diabetes (5.6)

Dyslipidemia: Undesirable alterations in lipid levels have been observed in patients treated with atypical antipsychotics (5.6)

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