

Width: 20.1 in

Length: 23.95 in

Final Fold: 1.5 in x 3 in
Number of panels: 13

ARIPRAZOLE- oral solution

Qugen Pharmaceuticals LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION

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

ARIPRAZOLE oral solution

Initial 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 oral solution is not approved for the treatment of patients with dementia-related psychosis (see **Warnings**, **Precautions**, and **Adverse Reactions**).

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 (see **Warnings**, **Precautions**, and **Adverse Reactions**).

INDICATIONS AND USAGE

Aripiprazole oral solution is an atypical antipsychotic. The oral formulations are indicated for:

- Schizophrenia (14.1)
- Acute Treatment of Manic and Mixed Episodes associated with Bipolar I (14.2)
- Adjunctive Treatment of Major Depressive Disorder (14.3)
- Intractability Associated with Autism Disorder (14.4)
- Treatment of Tourette's disorder (14.5)

DOSE AND ADMINISTRATION

Initial Dose Recommended Dose Maximum Dose

Schizophrenia - adults (2.1) 10 to 15 mg/day 10 mg/day 30 mg/day

Schizophrenia - adolescents (2.2) 2 mg/day 10 mg/day 30 mg/day

Bipolar mania - adults; monotherapy (2.2) 15 mg/day 15 mg/day 30 mg/day

Bipolar mania - adults; adjunct to lithium or valproate (2.2) 10 to 15 mg/day 15 mg/day 30 mg/day

Bipolar mania - pediatric patients; monotherapy or as an adjunct to lithium or valproate (2.2) 2 mg/day 10 mg/day 30 mg/day

Major depressive disorder - Adults; adjunct to antidepressant (2.3) 2 to 5 mg/day 5 to 10 mg/day 15 mg/day

Intractability 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 5 mg/day 10 mg/day

Oral Formulations: Administer once daily with regard to meals (2)

Known CYP2D6 Poor Metabolizers: Half of the usual dose (2.7)

DOSE FORMS AND STRENGTHS

Oral Solution: 1 mg/mL (3)

CONTRAINDICATIONS

Known hypersensitivity to aripiprazole (4)

WARNINGS AND PRECAUTIONS

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

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

Tardive Dyskinesia: Discontinue if clinically apparent (5.5)

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

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

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

Weight Gain: Weight gain has been observed with atypical antipsychotic use. Monitor weight (5.6)

Pathological Gambling and Other Compulsive Behaviors: Consider dose reduction or discontinuation (5.7)

Orthostatic Hypotension: Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope (5.8)

Leukopenia, Neutropenia, and Agranulocytosis: Have reported with antipsychotics including aripiprazole. Patients with a history of a clinically significant low white blood cell count (WBC), or a drug-induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of aripiprazole should be considered at the first sign of a clinically significant decrease in WBC in the absence of other causative factors (5.10)

Sources Consulted: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold (5.11)

Potential for Cognitive and Motor Impairment: Use caution when operating machinery (5.12)

Suicide: The possibility of a suicide attempt is inherent in schizophrenia and bipolar disorder. Closely supervise high-risk patients (5.14)

ADVERSE REACTIONS

Commonly observed adverse reactions (incidence ≥ 5% and at least twice that for placebo) were (6.1):

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers. Prescriptions for aripiprazole should be written for the smallest quantity consistent with good patient management, in order to reduce the risk of overdose.

Screening Patients for Bipolar Disorder: A major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone may increase the likelihood of precipitation of a mania/manic episode in patients at risk for bipolar disorder. Whether any of the symptoms described above represent such a conversion is unknown. However, prior to initiating treatment with an antidepressant, patients with depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; subsequent screening should be considered at the first sign of a clinically significant decrease in WBC in the absence of other causative factors (5.10)

Sources Consulted: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold (5.11)

Potential for Cognitive and Motor Impairment: Use caution when operating machinery (5.12)

Suicide: The possibility of a suicide attempt is inherent in schizophrenia and bipolar disorder. Closely supervise high-risk patients (5.14)

ADVERSE REACTIONS

Commonly observed adverse reactions (incidence ≥ 5% and at least twice that for placebo) were (6.1):

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

Patients with schizophrenia: akathisia

ARIPRAZOLE

oral solution

1 mg/mL

Rx Only

Rev. 09/25

20.1 in

1.5 in

1.5 in

1.2 in

3 in

1.5 in

1.5 in

1.5 in

1.5 in

1.5 in

1.5 in

1.5 in

1.5 in

1.5 in



94 Country Line Rd, STE B, Colmar, PA 18915, Ph.:+1 267 768 8538
www.adiyapharma.com | info@adiyapharma.com

APPROVAL SHEET

Artwork No. : 251227

Customer Name : Quagen Pharmaceuticals LLC

Customer Rep : Mr. Naresh Chintalapati Date Submitted : Nov 19, 2025

JOB INFO

Job Name : 52032 ARIPIPRAZOLE Oral Solution

Type : New Design ☒ Reprint ☐

File Name : 52032 ARIPIPRAZOLE Oral Solution (Quagen)

Job Type : Outsert ☒ Med Guide ☐ Patient Guide ☐

Revision : 09/25 Proof # : 07 Nov 19, 2025 01:00 PM

Grain Direction : See the Artwork

Manufacture by : Adiya Pharma Manufacture for : Quagen Pharmaceuticals LLC

Font Size : 6 pt Flat Size : L 23.95" x W 20.1"

Final folded size : 1.5" x 3"

Customer Item # : 52032 Barcode Reader : 52032

Paper Stock : 27# Pharmopaque Barcode Type : Code 128

Ink : Black

NOTES

APPROVED: OK to Print ☐

DATE: Approved By:

* Please review in detail for Layout, Content, Spelling, Spacing, Grammar, Structures, Colors, Barcode and all Specs related to his Artwork.
Adiya Pharma Inc. is not responsible for errors on printed products that appear on this proof.