OPIPZA™
(aripiprazole) oral film

2 mg 5 mg 10 mg

INDICATION

OPIPZA is an atypical antipsychotic indicated for:[1]

- treatment of schizophrenia in patients ages 13 years and older
- adjunctive treatment of major depressive disorder (MDD) in adults
- irritability associated with autistic disorder in pediatric patients 6 years and older
- treatment of Tourette's disorder in pediatric patients 6 years and older

DOSAGE AND ADMINISTRATION[1]

		Initial Starting Dosage	Recommended Dosage	Maximum Dosage
Schizophrenia (adults)		10 to 15 mg/day	10 to 15 mg/day	30 mg/day
Schizophrenia – (pediatric patients 13 years and older)		2 mg/day	10 mg/day	30 mg/day
Adjunctive Treatment of Major Depressive Disorder [MDD] (adults)		2 to 5 mg/day	5 to 10 mg/day	15 mg/day
Irritability associated with Autistic Disorder (pediatric patients 6 years and older)		2 mg/day	5 to 10 mg/day	15 mg/day
Tourette's disorder (pediatric patients 6 years and older)	< 50 kg (~110 lbs)	2 mg/day	5 mg/day	10 mg/day
	≥ 50 kg (~110 lbs)	2 mg/day	10 mg/day	20 mg/day

*Known CYP2D6 poor metabolizers: Administer half of the recommended dosage

IMPORTANT SAFETY INFORMATION ABOUT OPIPZA

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

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. OPIPZA is not approved for the treatment of patients with dementia-related psychosis *[see Warnings and Precautions]*.

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors *[see Warnings and Precautions]*.

CONTRAINDICATIONS

- Known hypersensitivity to aripiprazole

WARNINGS AND PRECAUTIONS

- Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis: Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities)
- Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring
- Tardive Dyskinesia: Discontinue if clinically appropriate
- Metabolic Changes: Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain
- Pathological Gambling and Other Compulsive Behaviors: Consider dose reduction or discontinuation

Please see additional Important Safety Information on back and Full Prescribing Information, including Boxed Warning and Medication Guide.

carwin PHARMACEUTICAL ASSOCIATES

References: 1. OPIPZA™ (aripiprazole) oral film [prescribing information]. Hazlet, NJ: 2024.

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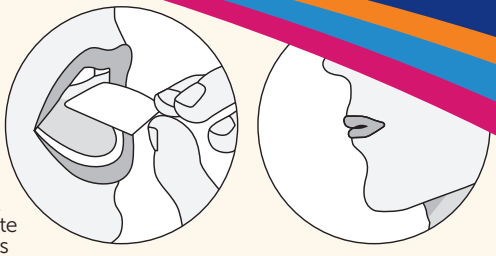
ADMINISTRATION[1]

- Dissolve on top of tongue once daily with or without food
- OPIPZA will dissolve in saliva and can be swallowed in a normal manner without the need for water and other liquids
- The patient should refrain from chewing the film and should not swallow an undissolve film. Do not cut or split OPIPZA.
- Administer only one oral film at a time. If an additonal film is needed to complete the dosage, administer after the previous film has completely dissolved.



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IMPORTANT SAFETY INFORMATION WARNINGS AND PRECAUTIONS (cont'd)

- Orthostatic Hypotension and Syncope: Monitor heart rate and blood pressure and caution patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope
- Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood cell counts (CBC) in patients with a history of a clinically significant low white blood cell count (WBC) or a history of leukopenia or neutropenia.
- Consider discontinuing OPIPZA if clinically significant decline in WBC in the absence of other causative factors
- Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold
- Potential for Cognitive and Motor Impairment: Use caution when operating machinery

ADVERSE REACTIONS

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

- Schizophrenia (adults): akathisia
- Schizophrenia (pediatric patients 13 to 17 years): extrapyramidal disorder, somnolence, and tremor
- Adjunctive treatment of MDD (adults): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision
- Irritability associated with autistic disorder (pediatric 6 years and older): sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder, and lethargy
- Tourette's disorder (pediatric patients 6 years and older): sedation, somnolence, nausea, headache, nasopharyngitis, fatigue, increased appetite

DRUG INTERACTIONS

Dosage adjustments for patients taking CYP2D6 inhibitors, CYP3A4 inhibitors, or CYP3A4 inducers

Factors	Dosage Recommendations
CYP2D6 Poor Metabolizers taking strong CYP3A4 inhibitors	Administer a quarter of recommended dosage
Strong CYP2D6 or CYP3A4 inhibitors	Administer half of recommended dosage
Strong CYP2D6 and CYP3A4 inhibitors	Administer a quarter of recommended dosage
Strong CYP3A4 inducers	Double the recommended dosage over 1 to 2 weeks

USE IN SPECIFIC POPULATIONS

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

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