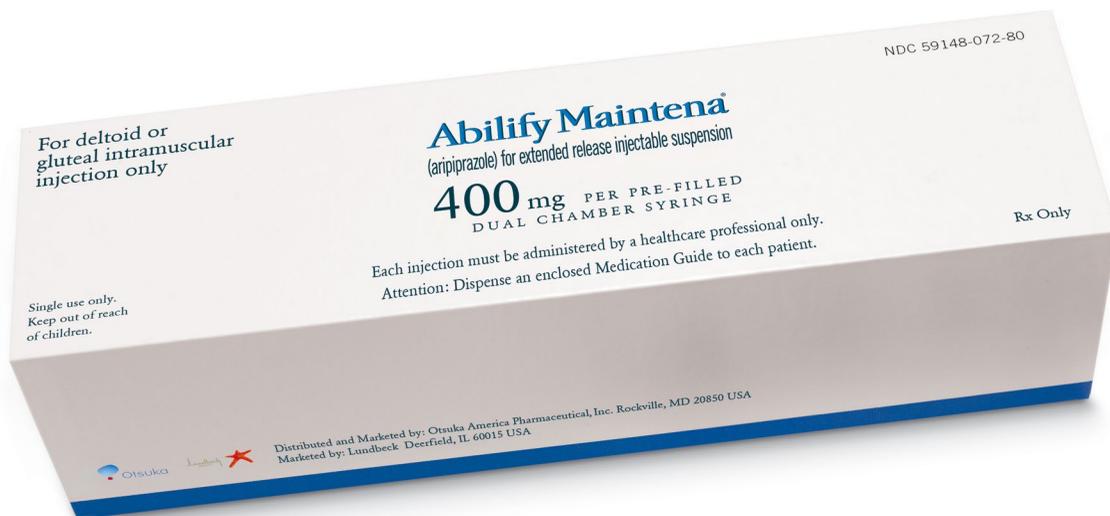


## Dosing and administration information for ABILIFY MAINTENA® (aripiprazole)

Approved for deltoid or gluteal administration



### INDICATIONS

ABILIFY MAINTENA® (aripiprazole) is an atypical antipsychotic indicated for:

- Treatment of schizophrenia in adults
- Maintenance monotherapy treatment of bipolar I disorder in adults

### WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at increased risk of death (1.6 to 1.7 times) compared to placebo-treated patients. ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis.

Please see [IMPORTANT SAFETY INFORMATION](#) on pages 6 and 7.





## ABILIFY MAINTENA® (aripiprazole) is available in both pre-filled, dual chamber syringe and vial kit options

The pre-filled, dual chamber syringe (DCS) features an all-in-one delivery system that decreases the number of steps required for reconstitution compared with the vial kit



- ▶ 400 mg and 300 mg dosing options
- ▶ Administer within 30 minutes after reconstitution of pre-filled DCS
- ▶ Room temperature storage\*

Vial kits will continue to be available for patients requiring dosages other than 400 mg or 300 mg



- ▶ In general, no dosage adjustments for ABILIFY MAINTENA are required based on age alone,<sup>†</sup> gender, race, smoking status, hepatic function, or renal function

\*DCS: Store below 30°C [86°F]. Do not freeze. Protect the syringe from light by storing in the original package until time of use.  
Vial kit: Store at 25°C (77°F); excursions permitted between 15°C and 30°C (59°F to 86°F) [see USP Controlled Room Temperature].  
<sup>†</sup> The safety and effectiveness of ABILIFY MAINTENA in patients >65 years of age have not been adequately evaluated.

### Important Warning and Precaution Regarding Cerebrovascular Adverse Events, Including Stroke:

Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, have been reported in clinical trials of elderly patients with dementia-related psychosis treated with oral aripiprazole.

Please see [IMPORTANT SAFETY INFORMATION](#) on pages 6 and 7.



## For some patients, dosage adjustments are recommended

Dosage adjustments are based on patient's CYP2D6 metabolism or use of concomitant medications

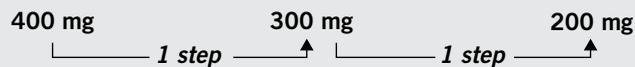
### DOSAGE ADJUSTMENTS

1 CYP2D6 poor metabolizer

2 Receiving CYP2D6 inhibitors for more than 14 days

3 Receiving CYP3A4 inhibitors for more than 14 days

The presence of 1 of the above criteria necessitates a 1-step dosage reduction



The presence of criteria 1 and 3 or 2 and 3 necessitates a 2-step dosage reduction



- ▶ For patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for more than 14 days
- ▶ Avoid the concomitant use of CYP3A4 inducers with ABILIFY MAINTENA for more than 14 days

**Because dosage adjustments cannot be made with the 400 mg or 300 mg DCS, vial kits need to be specifically requested.**

**Important Warning and Precaution Regarding Tardive Dyskinesia (TD):** Risk of TD, and the potential to become irreversible, are believed to increase with duration of treatment and total cumulative dose of antipsychotic drugs. TD can develop after a relatively brief treatment period, even at low doses, or after discontinuation of treatment. Prescribing should be consistent with the need to minimize TD. If antipsychotic treatment is withdrawn, TD may remit, partially or completely.

Please see [IMPORTANT SAFETY INFORMATION](#) on pages 6 and 7.

# INDICATIONS and IMPORTANT SAFETY INFORMATION for ABILIFY MAINTENA® (aripiprazole)

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## INDICATIONS

ABILIFY MAINTENA is an atypical antipsychotic indicated for:

- Treatment of schizophrenia in adults
- Maintenance monotherapy treatment of bipolar I disorder in adults

## IMPORTANT SAFETY INFORMATION

### WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

**Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at increased risk of death (1.6 to 1.7 times) compared to placebo-treated patients. ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis.**

**Contraindication:** Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.

**Cerebrovascular Adverse Events, Including Stroke:** Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, have been reported in clinical trials of elderly patients with dementia-related psychosis treated with oral aripiprazole.

**Neuroleptic Malignant Syndrome (NMS):** NMS is a potentially fatal symptom complex reported in association with administration of antipsychotic drugs including ABILIFY MAINTENA. Clinical signs of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability. Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Manage NMS with immediate discontinuation of ABILIFY MAINTENA, intensive symptomatic treatment, and monitoring.

**Tardive Dyskinesia (TD):** Risk of TD, and the potential to become irreversible, are believed to increase with duration of treatment and total cumulative dose of antipsychotic drugs. TD can develop after a relatively brief treatment period, even at low doses, or after discontinuation of treatment. Prescribing should be consistent with the need to minimize TD. If antipsychotic treatment is withdrawn, TD may remit, partially or completely.

**Metabolic Changes:** Atypical antipsychotic drugs have caused metabolic changes including:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Patients with diabetes mellitus should be regularly monitored for worsening of glucose control; those with risk factors for diabetes (e.g., obesity, family history of diabetes), should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

**Pathological Gambling and Other Compulsive Behaviors:** Intense urges, particularly for gambling, and the inability to control these urges have been reported while taking aripiprazole. Other compulsive urges have been reported less frequently. Prescribers should ask patients or their caregivers about the development of new or intense compulsive urges. Consider dose reduction or stopping aripiprazole if such urges develop.

**Orthostatic Hypotension:** ABILIFY MAINTENA may cause orthostatic hypotension and should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

*continued on next page*

Please see [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**.

## IMPORTANT SAFETY INFORMATION for ABILIFY MAINTENA® (aripiprazole) (continued)

**Falls:** Antipsychotics may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls causing fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating treatment and recurrently during therapy.

**Leukopenia, Neutropenia, and Agranulocytosis:** Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC)/absolute neutrophil count or history of drug-induced leukopenia/neutropenia. Discontinue ABILIFY MAINTENA at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

**Seizures:** ABILIFY MAINTENA should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

**Potential for Cognitive and Motor Impairment:** ABILIFY MAINTENA may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery, including automobiles, until they are certain ABILIFY MAINTENA does not affect them adversely.

**Body Temperature Regulation:** Use ABILIFY MAINTENA with caution in patients who may experience conditions that increase body temperature (e.g., strenuous exercise, extreme heat, dehydration, or concomitant use with anticholinergics).

**Dysphagia:** Esophageal dysmotility and aspiration have been associated with ABILIFY MAINTENA. Use caution in patients at risk for aspiration pneumonia.

**Alcohol:** Advise patients to avoid alcohol while taking ABILIFY MAINTENA.

**Concomitant Medication:** Dosage adjustments are recommended in patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for greater than 14 days. Avoid concomitant use of CYP3A4 inducers with ABILIFY MAINTENA for greater than 14 days. Dosage adjustments are not recommended for patients with concomitant use of CYP3A4 inhibitors, CYP2D6 inhibitors or CYP3A4 inducers for less than 14 days.

**Most Commonly Observed Adverse Reactions:** The most commonly observed adverse reactions with ABILIFY MAINTENA in patients with schizophrenia (incidence  $\geq 5\%$  and at least twice that for placebo) were increased weight, akathisia, injection site pain, and sedation.

**Injection Site Reactions:** In a short-term, clinical trial with ABILIFY MAINTENA in patients with schizophrenia treated with gluteal administered ABILIFY MAINTENA, the percent of patients reporting any injection site-related adverse reaction was 5.4%, and 0.6% for placebo. In an open label study of ABILIFY MAINTENA administered in the deltoid or gluteal muscle, injection site pain was observed at approximately equal rates.

**Dystonia:** Symptoms of dystonia may occur in susceptible individuals during the first days of treatment and at low doses.

**Pregnancy:** Neonates exposed to antipsychotic drugs, including ABILIFY MAINTENA, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms. Consider the benefits and risks of ABILIFY MAINTENA and possible risks to the fetus when prescribing ABILIFY MAINTENA to a pregnant woman. Advise pregnant women of potential fetal risk.

**Lactation:** Aripiprazole is present in human breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother and any potential risks to the infant.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)).

Please see [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**.

## ABILIFY MAINTENA® (aripiprazole) provides options for administration



- ▶ A single 400 mg, once-monthly\* dose is recommended for both starting and maintenance
- ▶ Provide the flexibility of deltoid or gluteal administration options
- ▶ Available in both a pre-filled, dual chamber syringe (DCS) for all-in-one delivery and vial kit
- ▶ 300 mg and 400 mg vial kits are available for patients needing dosage adjustments

\*Establish tolerability with oral aripiprazole before initiating therapy. Along with the first injection, patients should take oral aripiprazole or current oral antipsychotic for 14 consecutive days.

Please specify either DCS or vial kit when writing for both conventional and electronic prescriptions.

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