Seizures: in patients with severe neutropenia (ANC <1000/mm³) and follow their WBC counts until recovery. Signs of infection and treat promptly if such symptoms or signs occur. Discontinue ABILIFY MAINTENA at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or absolute neutrophil count (ANC) or history of drug-induced leukopenia/neutropenia, perform a complete blood count (CBC) frequently during the first few months of therapy. Consider discontinuing ABILIFY MAINTENA® (aripiprazole) for extended release injectable suspension.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis have been reported. In patients with a history of clinically significant low white blood cell count (WBC)/neutrophil count, perform a complete blood count (CBC) frequently during the first few months of therapy. Consider discontinuing ABILIFY MAINTENA at the first sign of a clinically significant decline in WBC in the absence of other causative factors.

IMPORTANT SAFETY INFORMATION (CONT’D)

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc.

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.

Pregnancy: ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis.

Most Commonly Observed Adverse Reactions:

In short-term, double-blind, placebo-controlled trials, adverse reactions, except those related to extrapyramidal symptoms, occurred at an incidence of 1% or more in patients treated with aripiprazole that was greater than placebo. The incidence of adverse reactions in patients treated with ABILIFY MAINTENA (incidence of 5% or greater and aripiprazole incidence at least twice that for placebo) was increased weight (16.8% vs 7.0%), akathisia (11.4% vs 3.5%), and sedation (5.4% vs 1.2%). The most commonly observed adverse reactions in short-term, double-blind, placebo-controlled trials (1% or greater in patients treated with ABILIFY MAINTENA and incidence greater than placebo) were akathisia (5.4% vs 1.2%), sedation (5.4% vs 1.2%), extrapyramidal symptoms (EPS) (5.4% vs 1.2%), dizziness (4.5% vs 2.4%), and insomnia (4.2% vs 2.4%). In randomized, double-blind, placebo-controlled trials of ABILIFY MAINTENA in patients with dementia-related psychosis, EPS was reported at a higher rate in patients treated with ABILIFY MAINTENA (incidence of 5% or greater) than in patients treated with placebo (3.3%).

Abnormal Involuntary Movement: Abnormal involuntary movement, including parkinsonian manifestations and tardive dyskinesia, were reported more frequently in patients treated with ABILIFY MAINTENA (incidence of 5% or greater) than in placebo controls. The incidence of extrapyramidal symptoms was similar in placebo and active control groups (1% or greater in patients treated with ABILIFY MAINTENA and incidence greater than placebo).

Dystonia: Symptoms of dystonia may occur in susceptible individuals during the first days of treatment with ABILIFY MAINTENA. Dystonia may occur in patients with dystonia and use of aripiprazole, and dystonia may occur at any time during treatment with ABILIFY MAINTENA. Advise patients about the possibility of dystonia and to report symptoms to their healthcare provider.

Diabetes Mellitus: Hyperglycemia, hyperosmolar hyperketosis, and diabetic ketoacidosis have been reported with antipsychotic use and may range in severity. Monitor patients with diabetes mellitus or risk factors for diabetes mellitus for changes in glucose levels.

Disruption of the Body’s Ability to Reduce Core Body Temperature: Disruption of the body’s ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.

Body Temperature Regulation: Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, may use caution in patients at risk for aspiration pneumonia.

Dysphagia: Esophageal dysmotility and dysphagia have been associated with ABILIFY MAINTENA. Instruct patients in appropriate care, including small frequent meals, slow swallowing, and use of a soft diet as necessary.

Hypertension: Blood pressure should be monitored periodically in elderly patients treated with antipsychotics, including ABILIFY MAINTENA. Monitor the blood pressure in elderly patients, especially those with cardiovascular disease.

Extrapyramidal and/or withdrawal symptoms: Neoplasms: Neoplasms have been reported with antipsychotics. Monitor patients with a history of cancer for recurrence of neoplasms.

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.

Dosing and administration information for ABILIFY MAINTENA® (aripiprazole) is an atypical antipsychotic indicated for the treatment of schizophrenia.

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

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. 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) offers the flexibility of deltoid or gluteal administration

Provide options for administration

- Choose from 3 needle options—conveniently color-coded based on site of administration and size of patient
- Rotate site of injection between 2 deltoid or gluteal muscles
- Each box of ABILIFY MAINTENA offers needle options for deltoid and gluteal administration—no additional ordering needed
- Following multiple doses, there is a gradual rise of aripiprazole to maximum plasma concentrations (T_max) at a median of 4 days for the deltoid muscle and 5-7 days for the gluteal muscle

Each injection of ABILIFY MAINTENA contains one active ingredient*—aripiprazole—suspended in sterile water

- In an open-label study comparing bioavailability of ABILIFY MAINTENA administered into the deltoid vs gluteal muscle, injection site pain was observed at approximately equal rates
- In the short-term, double-blind, placebo-controlled trial, the percentage of patients reporting any injection site-related adverse reaction (all reported as injection site pain) was 5.4% for patients treated with gluteal-administered ABILIFY MAINTENA and 0.6% for placebo

*Inactive ingredients: carboxymethyl cellulose sodium, mannitol, sodium phosphate monobasic monohydrate, and sodium hydroxide.

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

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, 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.
† The safety and effectiveness of ABILIFY MAINTENA in patients >65 years of age have not been adequately evaluated.
See Warning and Precaution Regarding Increased Mortality in Elderly Patients with Dementia-Related Psychosis in accompanying FULL PRESCRIBING INFORMATION for ABILIFY MAINTENA.

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.
A single 400 mg, once-monthly dose is recommended for both initiation and maintenance

- **ABILIFY MAINTENA®** (aripiprazole) is to be administered by either deep intramuscular deltoid or gluteal injection by a **healthcare professional**
- For patients who have never taken aripiprazole, establish tolerability with oral aripiprazole prior to initiating treatment with ABILIFY MAINTENA — Due to the half-life of oral aripiprazole, it may take up to 2 weeks to fully assess tolerability
- After the first injection of ABILIFY MAINTENA, treatment with oral aripiprazole (10 mg to 20 mg) or current oral antipsychotic should be continued for 14 consecutive days

### Important Warning and Precaution Regarding Neuroleptic Malignant Syndrome (NMS):

A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including ABILIFY MAINTENA. Rare cases of NMS occurred during aripiprazole treatment. Signs and symptoms of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (e.g., irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

### Dosage Adjustments

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

#### CYP2D6 poor metabolizer

1. Receiving CYP2D6 inhibitors for more than 14 days

| The presence of 1 of the above criteria necessitates a 1-step dosage reduction |
|-----------------------------|-----------------------------|-----------------------------|
| 400 mg | 300 mg | 200 mg |
| 1 step | 1 step | 1 step |

#### Receiving CYP3A4 inhibitors or CYP2D6 inhibitors for more than 14 days

| The presence of criteria 1 and 3 or 2 and 3 necessitates a 2-step dosage reduction |
|-----------------------------|-----------------------------|-----------------------------|
| 400 mg | 300 mg | 200 mg | 160 mg |
| 2 steps | 2 steps | 2 steps |

For patients who are CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for more than 14 days

- Concurrent antipsychotic treatment helps achieve or maintain therapeutic concentrations during initiation
- If there are adverse reactions with the 400 mg dosage, consider reducing the dosage to 300 mg
- Do not administer ABILIFY MAINTENA any sooner than 26 days after the previous injection

In the event of a missed dose, follow the instructions in the chart below

### MISSED DOSES

<table>
<thead>
<tr>
<th>Which dose was missed?</th>
<th>How much time has passed since the last injection?</th>
<th>Next steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Second or third dose</td>
<td>&gt;4 weeks and &lt;5 weeks</td>
<td>Administer injection as soon as possible</td>
</tr>
<tr>
<td></td>
<td>&gt;5 weeks</td>
<td>Restart concomitant oral aripiprazole for 14 days with the next administered injection</td>
</tr>
<tr>
<td>Fourth dose or any dose thereafter</td>
<td>&gt;4 weeks and &lt;6 weeks</td>
<td>Administer injection as soon as possible</td>
</tr>
<tr>
<td></td>
<td>&gt;6 weeks</td>
<td>Restart concomitant oral aripiprazole for 14 days with the next administered injection</td>
</tr>
</tbody>
</table>

For some patients, dosage adjustments are recommended

Important Warning and Precaution Regarding Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Important Warning and Precaution Regarding Neuroleptic Malignant Syndrome (NMS): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including ABILIFY MAINTENA. Rare cases of NMS occurred during aripiprazole treatment. Signs and symptoms of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (e.g., irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

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

Please see IMPORTANT SAFETY INFORMATION on pages 6 and 7.
INDICATION and IMPORTANT SAFETY INFORMATION for ABILIFY MAINTENA® (aripiprazole)

INDICATION

ABILIFY MAINTENA® (aripiprazole) is an atypical antipsychotic indicated for the treatment of schizophrenia.

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 an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious in nature. 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): A potentially fatal symptom complex sometimes referred to as NMS may occur with administration of antipsychotic drugs, including ABILIFY MAINTENA. Rare cases of NMS occurred during aripiprazole treatment. Signs and symptoms of NMS include hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (e.g., irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent treatment; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal, involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Prescribing should be consistent with the need to minimize TD. There is no known treatment for established TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include:

- Hyperglycemia/Diabetes Mellitus: Hyperglycemia, in some cases extreme and associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Patients with diabetes should be regularly monitored for worsening of glucose control; those with risk factors for 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 associated with 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 (e.g., eating, sexual, or shopping) have been reported less frequently. Prescribers should ask patients or their caregivers specifically about, and closely monitor for, 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.

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. In patients with a history of clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC) or history of drug-induced leukopenia/neutropenia, perform a complete blood count (CBC) frequency during the first few months of therapy. Consider discontinuing ABILIFY MAINTENA at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or signs of infection and treat promptly if such symptoms or signs occur. Discontinue ABILIFY MAINTENA in patients with severe neutropenia (ANC <1000/mm³) and follow their WBC counts until recovery.

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: Disruption of the body’s ability to reduce core body temperature has been attributed to antipsychotic agents. Advise patients regarding appropriate care in avoiding overheating and dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

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. If the CYP3A4 inhibitor or CYP2D6 inhibitor is withdrawn, the ABILIFY MAINTENA dosage may need to be increased. Avoid the concomitant use of CYP3A4 inducers with ABILIFY MAINTENA for greater than 14 days because the blood levels of aripiprazole are decreased and may be below the effective levels. 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: Based on the placebo-controlled trial of ABILIFY MAINTENA in schizophrenia, the most commonly observed adverse reactions associated with the use of ABILIFY MAINTENA (incidence of 5% or greater and aripiprazole incidence at least twice that for placebo) were increased weight (16.8% vs 7.0%), akathisia (11.4% vs 3.5%), injection site pain (5.6% vs 0.6%), and sedation (5.4% vs 1.2%).

Injection Site Reactions: In the data from the short-term, double-blind, placebo-controlled trial with ABILIFY MAINTENA in patients with schizophrenia, the percent of patients reporting any injection site-related adverse reaction (all reported as injection site pain) was 5.4% for patients treated with gluteal administered ABILIFY MAINTENA and 0.6% for placebo. In an open label study comparing bioavailability of ABILIFY MAINTENA administered in the deltoid or gluteal muscle, injection site pain was observed in both groups 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 extrapiramidal and/or withdrawal symptoms. These complications have varied in severity, from being self-limited to requiring intensive care and prolonged hospitalization. ABILIFY MAINTENA should be used during pregnancy only if the potential benefits justify the potential risks to the fetus.

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).

Please see FULL PRESCRIBING INFORMATION, including BOXED WARNING, for ABILIFY MAINTENA.
Seizures: in patients with severe neutropenia (ANC <1000/mm³) and follow their WBC counts until recovery. Signs of infection and treat promptly if such symptoms or signs occur. Discontinue ABILIFY MAINTENA at the first sign of a clinically significant decline in WBC in the absence of other causative factors. Monitor patients with clinically significant neutropenia for fever or other symptoms or complete blood count (CBC) frequently during the first few months of therapy. Consider discontinuing absolute neutrophil count (ANC) or history of drug-induced leukopenia/neutropenia, perform a.

Leukopenia, Neutropenia, and Agranulocytosis:

Falls:

Antipsychotics may cause somnolence, postural hypotension, motor and sensory instability, extrapyramidal symptoms (EPS), including akathisia, dyskinesia, tardive dyskinesia, and akathisia, an increase in symptoms of Parkinson's disease, including dystonia, or may exacerbate symptoms of movement disorder. Patients should be instructed to report symptoms suggestive of these adverse reactions. Risk of falls may be increased in patients with a history of falls, older patients, and those taking other drugs that can exacerbate these effects, complete fall risk assessments when initiating treatment and recurrently during therapy.

Pregnancy:

ABILIFY MAINTENA should be used during pregnancy only if the potential benefits justify the potential risks to the fetus.

Lactation:

It is not known whether ABILIFY MAINTENA is present in breast milk. The decision to use ABILIFY MAINTENA in a nursing woman should be made after considering the potential benefit of the drug to the mother and the potential risks to the nursing infant. Both mother and infant should be monitored closely.

Children:

The safety and effectiveness of ABILIFY MAINTENA in children and adolescents have not been established. ABILIFY MAINTENA is not approved for use in children or adolescents.

Alcohol:

These effects may be increased when using ABILIFY MAINTENA. Use caution in patients at risk for aspiration pneumonia.

Dysphagia:

Instruct patients to avoid swallowing the injection needle (oropharynx) or the oral suspension (esophagus) when administering ABILIFY MAINTENA. Instruct patients to swallow the needle (if indicated) and instruct patients to avoid swallowing the oral suspension if they cannot remove the needle (if indicated). ABILIFY MAINTENA is not approved for the treatment of patients with dysphagia.

Body Temperature Regulation:

ABILIFY MAINTENA may impair the body’s ability to maintain normal body temperature. Patients should be monitored and treated if body temperature rises above normal. Instruct patients to avoid exposure to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration. Appropriate care is advised for patients who may exercise strenuously, may be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or are subject to dehydration.

Symptoms of dystonia may occur in susceptible individuals during the first days of treatment with ABILIFY MAINTENA. This may be more likely to occur in patients who are old or has a history of dystonia or who have a history of antidepressant treatment. Instruct patients to contact their healthcare provider if symptoms of dystonia occur. If symptoms persist, discontinue ABILIFY MAINTENA.

Potential for Cognitive and Motor Impairment:

ABILIFY MAINTENA may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery, including automobiles, or engaging in activities requiring mental alertness or physical coordination until they are certain ABILIFY MAINTENA does not affect them adversely.

DOSING AND ADMINISTRATION GUIDE

A single 400 mg, once-monthly* dose is recommended for both initiation 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. *After the first injection of ABILIFY MAINTENA, treatment with oral aripiprazole or current oral antipsychotic should be continued for 14 consecutive days.

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

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

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). Although the causes of death were varied, most of the deaths appeared to be cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. ABILIFY MAINTENA is not approved for the treatment of patients with dementia-related psychosis.

Please see IMPORTANT SAFETY INFORMATION on pages 6 and 7 and FULL PRESCRIBING INFORMATION, including BOXED WARNING, for ABILIFY MAINTENA.