960MG

AbilifyAsimtufii®

(aripiprazole) extended release suspension for injection

For your adult patients living with schizophrenia

Aim for ABILIFY ASIMTUFII

ABILIFY ASIMTUFII offers two months of sustained plasma concentrations with a single dose,* giving your adult patients more time between doses to focus on what matters to them.[1]

Not an actual patient

* Based on a 32-week pharmacokinetic bridging study of ABILIFY MAINTENA® (aripiprazole) and ABILIFY ASIMTUFII in adults living with schizophrenia or bipolar I disorder.[1,2]

INDICATIONS

ABILIFY ASIMTUFII® (aripiprazole) is an atypical antipsychotic indicated for treatment of schizophrenia in adults and maintenance monotherapy treatment of bipolar I disorder in adults.

ABILIFY MAINTENA® (aripiprazole) is an atypical antipsychotic indicated for treatment of schizophrenia in adults and maintenance monotherapy treatment of bipolar I disorder in adults.

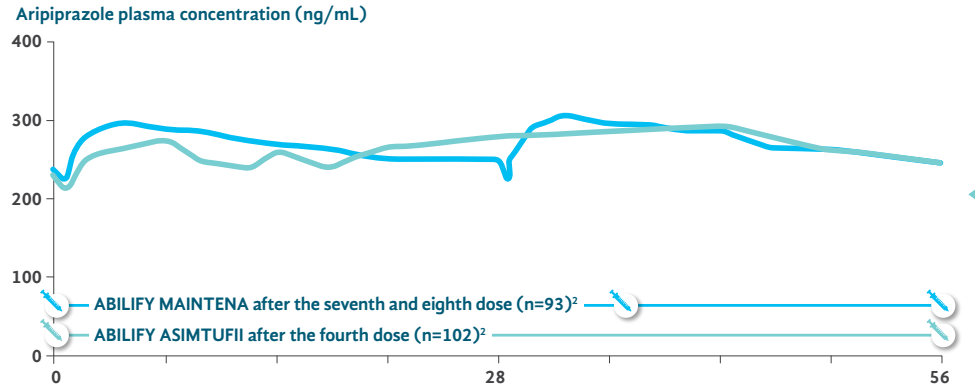
WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

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 ASIMTUFII and ABILIFY MAINTENA are not approved for the treatment of patients with dementia-related psychosis.

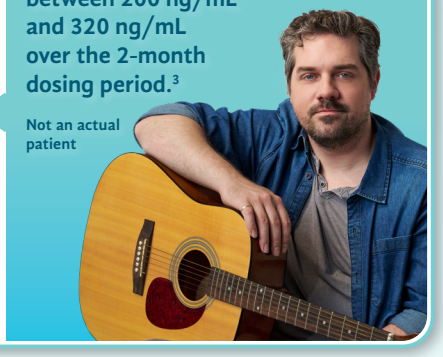
Please see IMPORTANT SAFETY INFORMATION, including BOXED WARNING, on page 4.

ABILIFY ASIMTUFII® (aripiprazole) offers two months of sustained plasma concentrations with a single dose[1]

Primary PK endpoint: Plasma concentration and AUC exposure of aripiprazole 56 days after the fourth dose of ABILIFY ASIMTUFII and 28 days after the eighth dose of ABILIFY MAINTENA® (aripiprazole) in adults with schizophrenia or bipolar I disorder.[2]



ABILIFY ASIMTUFII maintained aripiprazole plasma concentrations between 200 ng/mL and 320 ng/mL over the 2-month dosing period.[3]



Study design: 32-week, open-label, multiple-dose, randomized, parallel-arm, pharmacokinetic bridging study in stable† adults living with schizophrenia (n=185) or bipolar I disorder (n=81). Mean aripiprazole plasma concentrations were assessed after the fourth dose of ABILIFY ASIMTUFII vs the seventh and eighth doses of ABILIFY MAINTENA.[2]

The efficacy of ABILIFY ASIMTUFII is built on the pivotal studies of ABILIFY MAINTENA.[1]

ABILIFY MAINTENA **significantly improved symptoms** vs placebo in adults living with schizophrenia from baseline to Week 10 (treatment difference: −15.1 [95% CI −19.4 to −10.8]).[4]

Study design: Pivotal 12-week, randomized, double-blind, placebo-controlled study in acutely relapsed‡ adults living with schizophrenia. Patients were randomized to receive ABILIFY MAINTENA (n=168) or intramuscular placebo (n=172), with 14 days of oral aripiprazole or oral placebo after the first injection based on treatment arm. Safety was assessed throughout the duration of the study.[4] For this study, the primary endpoint was the mean change in PANSS total score from baseline to Week 10 vs placebo.[4‡]

ABILIFY MAINTENA **significantly delayed time to relapse**[§] vs placebo in adults living with schizophrenia (HR=0.199; 95% CI 0.10–0.30; *P*<0.0001).[5,6]

Study design: Pivotal 52-week, randomized, double-blind, placebo-controlled, maintenance study in adults living with schizophrenia (N=403). The study followed a 4-phase design: conversion to and stabilization on oral aripiprazole (phases 1–2), followed by conversion to and stabilization on ABILIFY MAINTENA 400 mg (phase 3), before entering the double-blind phase (phase 4).[5] For this study, the primary endpoint was time from randomization to relapse[§] vs placebo.[5]

AIM TO GIVE YOUR ADULT PATIENTS MORE TIME BETWEEN DOSES TO FOCUS ON WHAT MATTERS TO THEM

* Day 0 corresponds to the 24th week of the 32-week study.[2] † Clinically stable on oral aripiprazole, other antipsychotic, or ABILIFY MAINTENA.[1,2] ‡ Baseline characteristics: PANSS total score ≥80 and specific psychotic symptoms on the PANSS with a score >4 on each of the four specific items (conceptual disorganization, hallucinatory behavior, suspiciousness/persecution, and unusual thought content).[4] § Relapse was defined as one, or more, of the following: clinical worsening, psychiatric hospitalization, risk of suicide, or violent behavior.[5]
AUC=area under the concentration-time curve; CI=confidence interval; HR=hazard ratio; PANSS=Positive and Negative Syndrome Scale.

CONTRAINDICATION

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

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, including BOXED WARNING, on page 4.

Proven safety for your adult patients[1*]

ABILIFY ASIMTUFII® (aripiprazole) offers the established safety profile of ABILIFY MAINTENA® (aripiprazole)[1]

Adverse reactions, ≥2% population (12-week study of ABILIFY MAINTENA vs placebo in patients living with schizophrenia)[1†]

SYSTEM ORGAN CLASS	PREFERRED TERM	ABILIFY MAINTENA (%, n=167)	PLACEBO (%, n=172)
GASTROINTESTINAL DISORDERS	Constipation	10	7
	Dry mouth	4	2
	Diarrhea	3	2
	Vomiting	3	1
	Abdominal discomfort	2	1
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	Injection site pain	5	1
INFECTIONS AND INFESTATIONS	Upper respiratory tract infection	4	2
INVESTIGATIONS	Increased weight	17	7
	Decreased weight	4	2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	Arthralgia	4	1
	Back pain	4	2
	Myalgia	4	2
	Musculoskeletal pain	3	1
NERVOUS SYSTEM DISORDERS	Akathisia	11	4
	Sedation	5	1
	Dizziness	4	2
	Tremor	3	1
RESPIRATORY, THORACIC, AND MEDIASTINAL	Nasal congestion	2	1

● Most common adverse reactions (≥5% of patients and at least twice that for placebo)

ZERO DISCONTINUATIONS
due to the four most common adverse reactions[7]

In a 12-week study, **4.2% OF PATIENTS** on ABILIFY MAINTENA **DISCONTINUED** due to all adverse reactions, vs 7.6% with placebo[4]

* Clinically stable on oral antipsychotic or once-monthly ABILIFY MAINTENA.[1,8] † Table excludes adverse reactions that had an incidence ≤ placebo.[1]

IMPORTANT SAFETY INFORMATION for ABILIFY ASIMTUFII® (aripiprazole) and ABILIFY MAINTENA® (aripiprazole)

INDICATIONS

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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 ASIMTUFII and ABILIFY MAINTENA are 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 aripiprazole. 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 aripiprazole, 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 antidiabetic 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 or Syncope: ABILIFY ASIMTUFII and 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. Monitoring of orthostatic vital signs should be considered in patients who are vulnerable 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 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 ASIMTUFII or ABILIFY MAINTENA at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

Seizures: ABILIFY ASIMTUFII and 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 ASIMTUFII and ABILIFY MAINTENA may impair judgment, thinking, or motor skills. Patients should be cautioned about performing activities that require mental alertness such as operating hazardous machinery or operating a motor vehicle, until they are reasonably certain that therapy with ABILIFY ASIMTUFII or ABILIFY MAINTENA does not affect them adversely.

Body Temperature Regulation: Use ABILIFY ASIMTUFII or 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 aripiprazole. Use caution in patients at risk for aspiration.

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

Concomitant Medications: Dosage reductions are recommended in patients who are CYP2D6 poor metabolizers and/or in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors for greater than 14 days. Avoid concomitant use of CYP3A4 inducers with ABILIFY ASIMTUFII and 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 of ≥5% and at least twice that for placebo) were increased weight, akathisia, injection site pain, and sedation.

Injection Site Reactions:

- **ABILIFY MAINTENA:** In a short-term, clinical trial with ABILIFY MAINTENA in patients with schizophrenia treated with gluteally 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.
- **ABILIFY ASIMTUFII:** In an open-label study in patients with schizophrenia or bipolar I disorder, the percent of patients reporting any injection site-related adverse reactions was 19% for ABILIFY ASIMTUFII and 9.0% for ABILIFY MAINTENA. In both treatment groups, the majority of the injection site pain events coincided with the first injection and were reported with decreasing frequency upon subsequent injections. Patient-reported rating of pain was similar in both treatment groups at the last injection.

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 aripiprazole, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms. There are risks to the mother associated with untreated schizophrenia or bipolar I disorder and with exposure to antipsychotics, including ABILIFY ASIMTUFII and ABILIFY MAINTENA, during pregnancy.

Lactation: Aripiprazole is present in human breast milk. Monitor the breastfed infant for dehydration and lack of appropriate weight gain. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ABILIFY ASIMTUFII or ABILIFY MAINTENA and any potential adverse effects on the breastfed infant from ABILIFY ASIMTUFII or ABILIFY MAINTENA or from the underlying maternal condition.

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 ASIMTUFII and ABILIFY MAINTENA.

References: 1. ABILIFY ASIMTUFII® (aripiprazole) Prescribing Information. **2.** Harlin M, et al. A randomized, open-label, multiple-dose, parallel-arm, pivotal study to evaluate the safety, tolerability, and pharmacokinetics of aripiprazole 2-month long-acting injectable in adults with schizophrenia or bipolar I disorder. *CNS Drugs*. 2023;37:337–350. **3.** Data on file. ABIASI-023. **4.** Kane JM, et al. Aripiprazole once-monthly in the acute treatment of schizophrenia: findings from a 12-week, randomized, double-blind, placebo-controlled study. *J Clin Psychiatry*. 2014;75(11):1254–1260. **5.** Kane JM, et al. Aripiprazole intramuscular depot as maintenance treatment in patients with schizophrenia: a 52-week, multicenter, randomized, double-blind, placebo-controlled stud. *J Clin Psychiatry*. 2012;73(11):617–624. **6.** Data on file. ABIMAI-027. **7.** Data on file. ABIMAI-124. **8.** ABILIFY MAINTENA® (aripiprazole) Prescribing Information.

Otsuka Lundbeck

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