

 960MG
Abilify Asimtufii[®]
(aripiprazole) extended release
suspension for injection

Know when to aim for ABILIFY ASIMTUFII[®] (aripiprazole)

Luke, age 35
Diagnosis: schizophrenia

Luke's doctor determined he was ready for ABILIFY ASIMTUFII. He is:

- ✔ Managing a busy lifestyle
- ✔ Clinically stable on an oral antipsychotic but occasionally misses doses
 - In the past, this has led him to additional relapses or hospitalization with symptom reemergence, and prompted caregiver concerns
- ✔ Tolerant of aripiprazole
- ✔ Committed to the shared goal of extended time between doses

Discover how ABILIFY ASIMTUFII may help support your adult patients like Luke.

[**LEARN MORE**](#)

Not an actual patient

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.

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 is not approved for the treatment of patients with dementia-related psychosis.

IMPORTANT SAFETY INFORMATION for ABILIFY ASIMTUFII® (aripiprazole)

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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 ASIMTUFII. 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 ASIMTUFII, 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 or Syncope: ABILIFY ASIMTUFII 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 at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

Seizures: ABILIFY ASIMTUFII 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 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 does not affect them adversely.

Body Temperature Regulation: Use ABILIFY ASIMTUFII 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.

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 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 based on a 12-week study of a once monthly injection of aripiprazole in patients with schizophrenia (incidence of $\geq 5\%$ and at least twice that for placebo) were increased weight, akathisia, injection site pain, and sedation.

Injection Site Reactions: 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 once monthly aripiprazole injection. 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 ABILIFY ASIMTUFII, 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, 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 and any potential adverse effects on the breastfed infant from ABILIFY ASIMTUFII 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](#).

