2.4 Dosage in Bipolar I Disorder

The recommended starting dosage in adults with acute and mixed episodes associated with bipolar I disorder is 15 mg given once daily as monotherapy and 10 mg to 15 mg given once daily as adjunctive treatment with lithium or valproate. The recommended target dose of ABILIFY MYCITE is 15 mg daily, as monotherapy or as adjunctive treatment with lithium or valproate. The dosage may be increased to 30 mg daily based on clinical response. The maximum recommended daily dosage is 30 mg.

2.5 Dosage in Adjunctive Treatment of Major Depressive Disorder

The recommended starting dose for ABILIFY MYCITE as adjunctive treatment of adults with MDD taking an antidepressant is 2 to 5 mg daily. The recommended dosage range is 2 to 15 mg daily. Dosage adjustments of up to 5 mg daily should occur gradually, at intervals of no less than 1 week. The maximum recommended daily dosage is 15 mg. Periodically reassess to determine the continued need for maintenance treatment.

2.6 Dosage Adjustments for Cytochrome P450 Considerations

Dosage adjustments are recommended in patients who are known CYP2D6 poor metabolizers and in patients taking concomitant CYP3A4 inhibitors or CYP2D6 inhibitors or strong CYP3A4 inducers (see Table 1). When the coadministered drug is withdrawn from the combination therapy, ABILIFY MYCITE dosage should then be adjusted to its original level. When the coadministered CYP3A4 inducer is withdrawn, ABILIFY MYCITE dosage should be reduced to the original level over 1 to 2 weeks. Patients who may be receiving a combination of strong, moderate, and weak inhibitors of CYP3A4 and CYP2D6 (e.g., a strong CYP3A4 inhibitor and a moderate CYP2D6 inhibitor or a moderate CYP3A4 inhibitor with a moderate CYP2D6 inhibitor), the dosing may be reduced to one-quarter (25%) of the usual dose initially and then adjusted based on clinical response.

Table 1: Dose Adjustments for ABILIFY MYCITE in Patients Who Are Known CYP2D6 Poor Metabolizers and Patients Taking Concomitant CYP2D6 Inhibitors, 3A4 Inhibitors, and/or CYP3A4 Inducers

Factors	Dosage Adjustments for ABILIFY MYCITE
Known CYP2D6 Poor Metabolizers	Administer half of recommended dose
Known CYP2D6 Poor Metabolizers taking concomitant strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin)	Administer a quarter of recommended dose
Strong CYP2D6 (e.g., quinidine, fluoxetine, paroxetine) **or** CYP3A4 inhibitors (e.g., itraconazole, clarithromycin)	Administer half of recommended dose
Strong CYP2D6 **and** CYP3A4 inhibitors	Administer a quarter of recommended dose
Strong CYP3A4 inducers (e.g., carbamazepine, rifampin)	Double recommended dose over 1 to 2 weeks

When adjunctive ABILIFY MYCITE is administered to patients with major depressive disorder, ABILIFY MYCITE should be administered without dosage adjustment as specified in *[Dosage and Administration (2.5)].*

Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. There have been reports of hyperglycemia in patients treated with aripiprazole *[see Adverse Reactions (6.1, 6.2)]*. Assessment of the relationship between atypical antipsychotic use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of hyperglycemia-related adverse reactions in patients treated with the atypical antipsychotics.

Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. 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 during treatment with atypical antipsychotics should 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 atypical antipsychotic drug.

In an analysis of 13 placebo-controlled monotherapy trials in adults, primarily with schizophrenia or bipolar disorder, the mean change in fasting glucose in aripiprazole -treated patients (+4.4 mg/dL; median exposure 25 days; N=1057) was not significantly different than in placebo-treated patients (+2.5 mg/dL; median exposure 22 days; N=799). Table 4 shows the proportion of aripiprazole-treated patients with normal and borderline fasting glucose at baseline (median exposure 25 days) that had treatment-emergent high fasting glucose measurements compared to placebo-treated patients (median exposure 22 days).

Table 4: Changes in Fasting Glucose in Placebo-Controlled Monotherapy Trials in Adult Patients (Primarily Schizophrenia and Bipolar Disorder)

	Category Change (at least once) from Baseline	Treatment Arm	n/N	%
Fasting Glucose	Normal to High (<100 mg/dL to ≥126 mg/dL)	Aripiprazole	31/822	3.8
		Placebo	22/605	3.6
	Borderline to High (≥100 mg/dL and <126 mg/dL to ≥126 mg/dL)	Aripiprazole	31/176	17.6
		Placebo	13/142	9.2

At 24 weeks, the mean change in fasting glucose in aripiprazole-treated patients was not significantly different than in placebo-treated patients [+2.2 mg/dL (n=42) and +9.6 mg/dL (n=28), respectively].

The mean change in fasting glucose in adjunctive aripiprazole-treated patients with major depressive disorder (+0.7 mg/dL; median exposure 42 days; N=241) was not significantly different than in placebo-treated patients (+0.8 mg/dL; median exposure 42 days; N=246). Table 5 shows the proportion of adult patients with changes in fasting glucose levels from two placebo-controlled, adjunctive trials (median exposure 42 days) in patients with major depressive disorder.

Table 5: Changes in Fasting Glucose from Placebo-Controlled Adjunctive Trials in Adult Patients with Major Depressive Disorder

- *Metabolism and Nutrition Disorders: frequent* – anorexia; *rare* - hypokalemia, hyponatremia, hypoglycemia
- *Musculoskeletal and Connective Tissue Disorders: infrequent* - muscular weakness, muscle tightness; *rare* – rhabdomyolysis, mobility decreased
- *Nervous System Disorders: infrequent* - parkinsonism, memory impairment, cogwheel rigidity, hypokinesia, bradykinesia; *rare* – akinesia, myoclonus, coordination abnormal, speech disorder, grand mal convulsion; *<1/10,000* patients - choreoathetosis
- *Psychiatric Disorders: infrequent* – aggression, loss of libido, delirium; *rare* – libido increased, anorgasmia, tic, homicidal ideation, catatonia, sleep walking
- *Renal and Urinary Disorders: rare* - urinary retention, nocturia
- *Reproductive System and Breast Disorders: infrequent* - erectile dysfunction; *rare* – gynaecomastia, menstruation irregular, amenorrhea, breast pain, priapism
- *Respiratory, Thoracic, and Mediastinal Disorders: infrequent* - nasal congestion, dyspnea
- *Skin and Subcutaneous Tissue Disorders: infrequent* - rash, hyperhidrosis, pruritus, photosensitivity reaction, alopecia; *rare* - urticaria
- *Vascular Disorders: infrequent* – hypotension, hypertension

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of aripiprazole. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: occurrences of allergic reaction (anaphylactic reaction, angioedema, laryngospasm, pruritus/urticaria, or oropharyngeal spasm), pathological gambling, hiccups, blood glucose fluctuation, oculogyric crisis and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

7 DRUG INTERACTIONS

7.1 Drugs Having Clinically Important Interactions with ABILIFY MYCITE

Table 13 below includes clinically important drug interactions with ABILIFY MYCITE.

Table 13: Clinically Important Drug Interactions with ABILIFY MYCITE

Concomitant Drug Name or Drug Class	Clinical Rationale	Clinical Recommendation
Strong CYP3A4 Inhibitors (e.g., itraconazole, clarithromycin) or strong CYP2D6 inhibitors (e.g., quinidine, fluoxetine, paroxetine)	The concomitant use of aripiprazole with strong CYP3A4 or CYP2D6 inhibitors increased the exposure of aripiprazole compared to the use of aripiprazole alone *[see Clinical Pharmacology (12.3)]*.	With concomitant use of ABILIFY MYCITE with a strong CYP3A4 inhibitor or CYP2D6 inhibitor, reduce the ABILIFY MYCITE dosage *[see Dosage and Administration (2.6)]*.
Strong CYP3A4 Inducers (e.g., carbamazepine, rifampin)	The concomitant use of aripiprazole and carbamazepine decreased the exposure of aripiprazole compared to the use of aripiprazole alone *[see Clinical Pharmacology (12.3)]*.	With concomitant use of ABILIFY MYCITE with a strong CYP3A4 inducer, consider increasing the ABILIFY MYCITE dosage *[see Dosage and Administration (2.6)]*.
Antihypertensive Drugs	Due to its alpha adrenergic antagonism, aripiprazole has the potential to enhance the effect of certain antihypertensive agents.	Monitor blood pressure and adjust dose accordingly *[see Warnings and Precautions (5.8)]*.
Benzodiazepines (e.g., lorazepam)	The intensity of sedation was greater with the combination of oral aripiprazole	Monitor sedation and blood pressure. Adjust dose accordingly.

8.2 Lactation

Risk Summary

Aripiprazole is present in human breast milk; however, there are insufficient data to assess the amount in human milk, the effects on the breastfed infant, or the effects on milk production.

The development and health benefits of breastfeeding should be considered along with the mother's clinical need for ABILIFY MYCITE and any potential adverse effects on the breastfed infant from ABILIFY MYCITE or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness of ABILIFY MYCITE in pediatric patients have not been established.

Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric patients *[see Boxed Warning,and Warnings and Precautions (5.2)]*.

8.5 Geriatric Use

No dosage adjustment of ABILIFY MYCITE is recommended for elderly patients for the approved indications *[see Boxed Warning, Warnings and Precautions (5.1) and Clinical Pharmacology (12.3)]*.

Of the 13,543 patients treated with oral aripiprazole in clinical trials, 1073 (8%) were ≥65 years old and 799 (6%) were ≥75 years old. Placebo-controlled studies of oral aripiprazole in schizophrenia, bipolar mania, or major depressive disorder did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Elderly patients treated with antipsychotic drugs with dementia-related psychosis had a greater incidence of stroke and transient ischemic attack. ABILIFY MYCITE is not approved for the treatment of elderly patients with dementia-related psychosis *[see Boxed Warning and Warnings and Precautions (5.1, 5.3)]*.

8.6 CYP2D6 Poor Metabolizers

ABILIFY MYCITE dosage adjustment is recommended in known CYP2D6 poor metabolizers due to high aripiprazole concentrations. Approximately 8% of Caucasians and 3 to 8% of Black/African Americans cannot metabolize CYP2D6 substrates and are classified as poor metabolizers (PM) *[see Dosage and Administration (2.6) and Clinical Pharmacology (12.3)]*.

8.7 Hepatic and Renal Impairment

No dosage adjustment for ABILIFY MYCITE is required on the basis of a patient's hepatic function (mild to severe hepatic impairment, Child-Pugh score between 5 and 15) or renal function (mild to severe renal impairment, glomerular filtration rate between 15 and 90 mL/minute) *[see Clinical Pharmacology (12.3)]*.

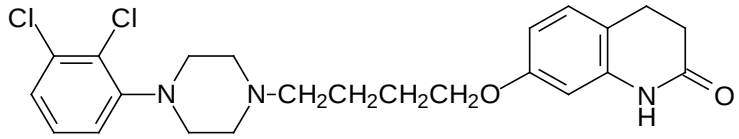
8.8 Other Specific Populations

No dosage adjustment for ABILIFY MYCITE is required on the basis of a patient's sex, race, or smoking status *[see Clinical Pharmacology (12.3)]*.

11 DESCRIPTION

ABILIFY MYCITE (aripiprazole tablets with sensor) is a drug-device combination product containing aripiprazole, an atypical antipsychotic, embedded with an Ingestible Event Marker (IEM) sensor.

Aripiprazole is 7-[4-[4-(2,3-dichlorophenyl)-1-piperazinyl]butoxy]-3,4-dihydrocarbostyril. The empirical formula is $C_{23}H_{27}Cl_2N_3O_2$ and its molecular weight is 448.38. The chemical structure is:



ABILIFY MYCITE is available in 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strength tablets with sensor. Inactive ingredients of the tablets with sensor include cornstarch, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. Colorants include ferric oxide (yellow or red) and FD&C Blue No. 2 Aluminum Lake. Ingredients of the IEM include aluminum, cuprous chloride, ethyl cellulose, gold, hydroxypropyl cellulose, magnesium, silicon, silicon dioxide, silicon nitride, titanium-tungsten, titanium and triethyl citrate.

The ABILIFY MYCITE System is a drug-device combination product composed of the following components:

- An aripiprazole tablet with an embedded Ingestible Event Marker (IEM) sensor. The IEM is a 1 mm sized sensor embedded in the ABILIFY MYCITE tablets with sensor. Upon contact with gastric fluid, magnesium and cuprous chloride within the IEM react to activate and power the device. The IEM then communicates to the MYCITE Patch, to track aripiprazole ingestion.
- A MYCITE Patch (wearable sensor) is designed to detect the ingestion of the ABILIFY MYCITE tablets with sensor, record the ingestion of the IEM, and transmit ingestion data to the mobile patient application (app).
- A compatible app displays this data to allow patients to review their medication ingestion. These data can be shared with healthcare providers and caregivers.
- Web-based portal or dashboard for healthcare professionals and caregivers.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

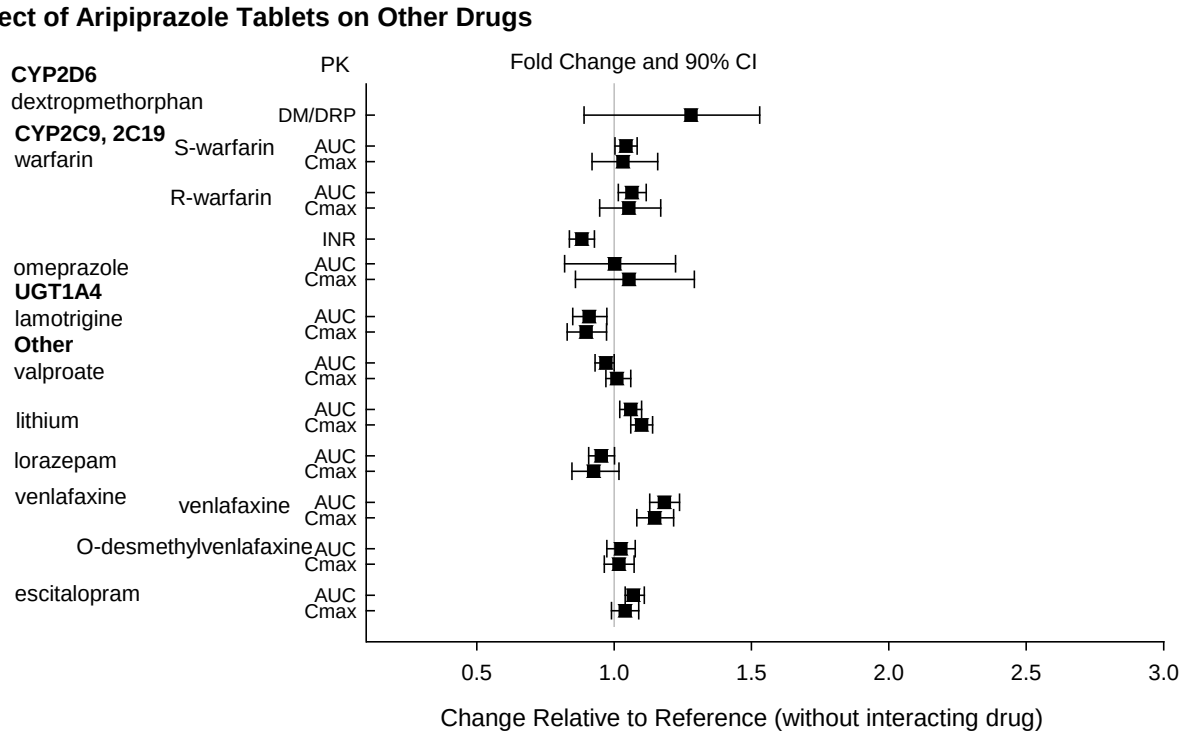
The mechanism of action of aripiprazole in the treatment of schizophrenia, bipolar I disorder, or adjunctive treatment of major depressive disorder is unknown. However, the efficacy of aripiprazole could be mediated through a combination of partial agonist activity at D_2 and 5-HT_{1A} receptors and antagonist activity at 5-HT_{2A} receptors.

12.2 Pharmacodynamics

Aripiprazole exhibits high affinity for dopamine D_2 and D_3, serotonin 5-HT_{1A} and 5-HT_{2A} receptors (K_i values of 0.34 nM, 0.8 nM, 1.7 nM, and 3.4 nM, respectively), moderate affinity for dopamine D_4, serotonin 5-HT_{2C} and 5-HT_7, alpha1-adrenergic and histamine H_1 receptors (K_i values of 44 nM, 15 nM, 39 nM, 57 nM, and 61 nM, respectively), and moderate affinity for the serotonin reuptake site (K_i=98 nM). Aripiprazole has no appreciable affinity for cholinergic muscarinic receptors (IC_{50}>1000 nM). Actions at receptors other than D_2, 5-HT_{1A}, and 5-HT_{2A} may explain some of the adverse reactions of aripiprazole (e.g., the orthostatic hypotension observed with aripiprazole may be explained by its antagonist activity at adrenergic alpha1 receptors).

150 mg/day) dosed to steady-state. The steady-state plasma concentrations of fluoxetine and norfluoxetine increased by about 18% and 36%, respectively, and concentrations of paroxetine decreased by about 27%. The steady-state plasma concentrations of sertraline and desmethylsertraline were not substantially changed when these antidepressant therapies were coadministered with aripiprazole.

Figure 3: The Effects of Aripiprazole on Pharmacokinetics of Other Drugs



Specific Populations

Exposures of aripiprazole and dehydro-aripiprazole in specific populations are summarized in Figure 4 and Figure 5, respectively.

What is ABILIFY MYCITE?

ABILIFY MYCITE is a prescription medicine of aripiprazole tablets with an Ingestible Event Marker (IEM) sensor inside it used:

- To treat adults with schizophrenia
- To treat bipolar I disorder:
  - short-term (acute) treatment of adults with manic or mixed episodes alone or when used with the medicine lithium or valproate
  - maintenance treatment of adults alone or when used with the medicine lithium or valproate
- To treat adults with major depressive disorder (MDD) along with other antidepressant medicines

The ABILIFY MYCITE System is meant to track if you have taken your ABILIFY MYCITE.

It is not known if ABILIFY MYCITE can improve how well you take your aripiprazole (patient compliance) or for changing your dose of aripiprazole.

There may be a delay in the detection of the ABILIFY MYCITE tablet and sometimes the detection of the tablet might not happen at all. ABILIFY MYCITE is not for use as real-time or emergency monitoring.

It is not known if ABILIFY MYCITE is safe or effective for use in children.

Do not take ABILIFY MYCITE if you are allergic to aripiprazole or any of the ingredients in ABILIFY MYCITE. See the end of this Medication Guide for a complete list of ingredients in ABILIFY MYCITE.

Before taking ABILIFY MYCITE, tell your healthcare provider about all your medical conditions, including if you:

- have diabetes or high blood sugar or have a family history of diabetes or high blood sugar. Your healthcare provider should check your blood sugar before you start and during treatment with ABILIFY MYCITE.
- have or had seizures (convulsions)
- have or had low or high blood pressure
- have or had heart problems or stroke
- have or had a low white blood cell count
- are pregnant or plan to become pregnant. Talk to your healthcare provider about the risk to your unborn baby if you take ABLIFY MYCITE during pregnancy.
    - Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with ABILIFY MYCITE.
    - If you become pregnant during treatment with ABILIFY MYCITE, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/.
- are breastfeeding or plan to breastfeed. ABILIFY MYCITE can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ABILIFY MYCITE.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ABILIFY MYCITE and other medicines may affect each other causing possible serious side effects. ABILIFY MYCITE may affect the way other medicines work, and other medicines may affect how ABILIFY MYCITE works.

Your healthcare provider can tell you if it is safe to take ABILIFY MYCITE with your other medicines. Do not start or stop any other medicines during treatment with ABILIFY MYCITE without talking to your healthcare provider first.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ABILIFY MYCITE?

- **See the MYCITE App for instructions about how to apply and wear the MYCITE Patch and how to use the ABILIFY MYCITE System the right way.**
- Take ABILIFY MYCITE exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking ABILIFY MYCITE without first talking to your healthcare provider.
- Take ABILIFY MYCITE by mouth with or without food.
- Swallow ABILIFY MYCITE tablets whole. Do not divide, crush, or chew ABILIFY MYCITE tablets.
- The ABILIFY MYCITE tablet is usually detected within 30 minutes after you take it, but there may be a delay of more than 2 hours for the smartphone app and web portal to detect that you have taken ABILIFY MYCITE, and sometimes the ABILIFY MYCITE tablet might not be detected at all. If the tablet is not detected after you take it, **do not** repeat the dose.
- If over-exposure occurs, call your poison control center at 1-800-222-1222.

What should I avoid while taking ABILIFY MYCITE?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how ABILIFY MYCITE affects you. ABILIFY MYCITE may make you drowsy.
- Do not become too hot or dehydrated during treatment with ABILIFY MYCITE.
  - Do not exercise too much.
  - In hot weather, stay inside in a cool place if possible.
  - Stay out of the sun.
  - Do not wear too much clothing or heavy clothing.
  - Drink plenty of water.

What are the possible side effects of ABILIFY MYCITE?

ABILIFY MYCITE may cause serious side effects, including:

- **See "What is the most important information I should know about ABILIFY MYCITE?"**
- **Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.**
- **Neuroleptic malignant syndrome (NMS), a serious condition that can lead to death.** Call your healthcare provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS:
  - high fever
  - stiff muscles
  - confusion
  - sweating
  - changes in pulse, heart rate, and blood pressure
- **Uncontrolled body movements (tardive dyskinesia).** ABILIFY MYCITE may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking ABILIFY MYCITE. Tardive dyskinesia may also start after you stop taking ABILIFY MYCITE.
- **Problems with your metabolism such as:**
  - **high blood sugar (hyperglycemia) and diabetes.** Increases in blood sugar can happen in some people who take ABILIFY MYCITE. Extremely high blood sugar can lead to coma or death. If you have diabetes or risk factors for diabetes (such as being overweight or a family history of diabetes), your healthcare provider should check your blood sugar before you start and during your treatment with ABILIFY MYCITE.

    Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with ABILIFY MYCITE:
    - **feel very thirsty**
    - **need to urinate more than usual**
    - **feel very hungry**
    - **feel weak or tired**
    - **feel sick to your stomach**
    - **feel confused, or your breath smells fruity**
  - **increased fat levels (cholesterol and triglycerides) in your blood.**
  - **weight gain.** You and your healthcare provider should check your weight regularly.
- **Unusual urges.** Some people taking ABILIFY MYCITE have had unusual urges, such as gambling, binge eating or eating that you cannot control (compulsive), compulsive shopping and sexual urges. If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider.

- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
- **Falls**
- **Low white blood cell count.** Your healthcare provider may do blood tests during the first few months of treatment with ABILIFY MYCITE.
- **Seizures (convulsions)**
- **Problems controlling your body temperature so that you feel too warm.** See "What should I avoid while taking ABILIFY MYCITE?"
- **Difficulty swallowing**

The most common side effects of ABILIFY MYCITE in adults include:

- restlessness or need to move (akathisia)
- dizziness
- nausea
- insomnia
- shaking (tremor)
- anxiety
- constipation
- sedation

These are not all the possible side effects of ABILIFY MYCITE.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ABILIFY MYCITE?

- Store ABILIFY MYCITE tablets at room temperature, between 68°F to 77°F (20°C to 25°C).
- Store MYCITE Patches between 41°F to 81°F (5°C to 27°C).
- Keep ABILIFY MYCITE tablets and MYCITE Patches (wearable sensor) dry. Do not store ABILIFY MYCITE tablets and Patches (wearable sensor) in places with high humidity.

Keep ABILIFY MYCITE and all medicines out of the reach of children.

General information about the safe and effective use of ABILIFY MYCITE.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ABILIFY MYCITE for a condition for which it was not prescribed. Do not give ABILIFY MYCITE to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about ABILIFY MYCITE that was written for healthcare professionals.

What are the ingredients in ABILIFY MYCITE?

Active ingredient: aripiprazole

Inactive ingredients: cornstarch, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose, and Ingestible Event Marker (IEM). Colorants include ferric oxide (yellow or red) and FD&C Blue No. 2 Aluminum Lake. Ingredients of the IEM include aluminum, cuprous chloride, ethyl cellulose, gold, hydroxypropyl cellulose, magnesium, silicon, silicon dioxide, silicon nitride, titanium-tungsten, titanium and triethyl citrate.

Manufactured by:
Tablets with embedded IEM sensors Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan
MYCITE Patches Manufactured for Otsuka America Pharmaceutical, Inc. 3956 Point Eden Way, Hayward, CA 94545 USA
Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850 USA
ABILIFY MYCITE® and MYCITE® are registered trademarks of Otsuka Pharmaceutical Company.

Otsuka
Otsuka America Pharmaceutical, Inc.

For more information about ABILIFY MYCITE go to www.abilifymycite.com or call 1-844-692-4834.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 12/2020