HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ABILIFY MYCITE safely and effectively. See full prescribing information for ABILIFY MYCITE.

ABILIFY MYCITE® (aripiprazole tablets with sensor), for oral use
Initial U.S. Approval: 2002

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDAL THOUGHTS AND BEHAVIORS
See full prescribing information for complete boxed warning.

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ABILIFY MYCITE is not approved for the treatment of patients with dementia-related psychosis. (5.1)**
- **Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor for worsening and emergence of suicidal thoughts and behaviors. (5.2)**
- **The safety and effectiveness of ABILIFY MYCITE have not been established in pediatric patients. (8.4)**

----------INDICATIONS AND USAGE----------
ABILIFY MYCITE, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, is indicated for the:

- Treatment of adults with schizophrenia (1)
- Treatment of bipolar I disorder (1)
  - Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate
  - Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate
- Adjunctive treatment of adults with major depressive disorder (MDD) (1)

Limitations of Use:

- The ability of ABILIFY MYCITE to improve patient compliance or modify aripiprazole dosage has not been established. (1)
- The use of ABILIFY MYCITE to track drug ingestion in "real-time" or during an emergency is not recommended because detection may be delayed or not occur. (1)

----------DOSAGE AND ADMINISTRATION----------

	Initial Dose	Recommended Dose	Maximum Dose
Schizophrenia – adults (2.3)	10 to 15 mg/day	10 to 15 mg/day	30 mg/day
Bipolar mania – adults: monotherapy (2.4)	15 mg/day	15 mg/day	30 mg/day
Bipolar mania – adults: adjunct to lithium or valproate (2.4)	10-15 mg/day	15 mg/day	30 mg/day
Major Depressive Disorder – Adults adjunct to antidepressants (2.5)	2 to 5 mg/day	5 to 10 mg/day	15 mg/day

- Administer once daily without regard to meals (2.2)
- Swallow whole; do not divide, crush, or chew (2.2)
- Known CYP2D6 poor metabolizers: Administer half of the usual dose (2.6)

----------DOSAGE FORMS AND STRENGTHS----------
Tablets with sensor: 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg (3)

----------CONTRAINDICATIONS----------
Known hypersensitivity to aripiprazole tablets (4)

----------WARNINGS AND PRECAUTIONS----------

- *Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis:* Increased incidence of cerebrovascular adverse reactions (e.g., stroke, transient ischemic attack, including fatalities) (5.3)
- *Neuroleptic Malignant Syndrome:* Manage with immediate discontinuation and close monitoring (5.4)
- *Tardive Dyskinesia:* Discontinue if clinically appropriate (5.5)
- *Metabolic Changes:* Monitor for hyperglycemia/diabetes mellitus, dyslipidemia, and weight gain (5.6)
- *Pathological Gambling and other Compulsive Behaviors:* Consider dose reduction or discontinuation (5.7)
- *Orthostatic Hypotension:* Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease, and risk of dehydration or syncope (5.8)
- *Leukopenia, Neutropenia, and Agranulocytosis:* Perform complete blood cell counts in patients with a history of a clinically significant low white blood cell count (WBC)/absolute neutrophil count (ANC). Consider discontinuation if clinically significant decline in WBC/ANC in the absence of other causative factors (5.10)
- *Seizures:* Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold (5.11)
- *Potential for Cognitive and Motor Impairment:* Use caution when operating machinery (5.12)

----------ADVERSE REACTIONS----------
Commonly observed adverse reactions (incidence ≥5% and at least twice that for placebo) in adult patients (6.1):

- Schizophrenia: akathisia
- Bipolar mania (monotherapy): akathisia, sedation, restlessness, tremor, and extrapyramidal disorder
- Bipolar mania (adjunctive therapy with lithium or valproate): akathisia, insomnia, and extrapyramidal disorder
- MDD (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision

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

----------DRUG INTERACTIONS----------
Dosage adjustment due to drug interactions and CYP2D6 poor metabolizers (7.1):

Factors	**Dosage Adjustments for ABILIFY MYCITE**
Known CYP2D6 Poor Metabolizers	Administer half recommended dose
Known CYP2D6 Poor Metabolizers and strong CYP3A4 inhibitors	Administer a quarter of recommended dose
Strong CYP2D6 **or** CYP3A4 inhibitors	Administer half recommended dose
Strong CYP2D6 **and** CYP3A4 inhibitors	Administer a quarter of recommended dose
Strong CYP3A4 inducers	Double recommended dose over 1 to 2 weeks

----------USE IN SPECIFIC POPULATIONS----------
Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure (8.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 2/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDAL THOUGHTS AND BEHAVIORS

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ABILIFY MYCITE is not approved for the treatment of patients with dementia-related psychosis *[see Warnings and Precautions (5.1)]*.

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors *[see Warnings and Precautions (5.2)]*. The safety and efficacy of ABILIFY MYCITE have not been established in pediatric patients *[see Use in Specific Populations (8.4)]*.

1 INDICATIONS AND USAGE

ABILIFY MYCITE, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, is indicated for the:

- Treatment of adults with schizophrenia *[see Clinical Studies (14.1)]*
- Treatment of bipolar I disorder
  - Acute treatment of adults with manic and mixed episodes as monotherapy and as adjunct to lithium or valproate *[see Clinical Studies (14.2)]*
  - Maintenance treatment of adults as monotherapy and as adjunct to lithium or valproate *[see Clinical Studies (14.2)]*
- Adjunctive treatment of adults with Major Depressive Disorder *[see Clinical Studies (14.3)]*

Limitations of Use:

- The ability of the ABILIFY MYCITE to improve patient compliance or modify aripiprazole dosage has not been established *[see Dosage and Administration (2.1)]*.
- The use of ABILIFY MYCITE to track drug ingestion in “real-time” or during an emergency is not recommended because detection may be delayed or not occur *[see Dosage and Administration (2.1)]*.

2 DOSAGE AND ADMINISTRATION

2.1 Overview of the ABILIFY MYCITE System

The ABILIFY MYCITE System is composed of the following components:

- Aripiprazole tablet embedded with an IEM sensor (ABILIFY MYCITE);
- MYCITE® Patch (wearable sensor) that detects the signal from the IEM sensor after ingestion and transmits data to a smartphone;
- MYCITE APP - a smartphone application (app) which is used with a compatible smartphone to display information for the patient;
- Web-based portal for healthcare professionals and caregivers

Prior to initial patient use of the ABILIFY MYCITE System, facilitate use of the combination product and its components (patch, app, portal) and ensure the patient is capable and willing to use smartphones and apps. Before using any component of the ABILIFY MYCITE System, instruct patients to:

- Download the MYCITE APP and follow all the Instructions for Use.
- Ensure that the app is compatible with their specific smartphone.

Although most ingestions will be detected within 30 minutes, it may take up to two hours for the smartphone app and web portal to detect the ingestion of ABILIFY MYCITE; in some cases, the ingestion of the tablet may not be detected. If the tablet is not detected after ingestion, do not repeat the dose *[see Adverse Reactions (6)]*.

The status of the MYCITE Patch is indicated by a status icon in the app to inform the user that the patch is properly adhered and fully functioning. Instruct patients to ensure that the app is paired with the patch prior to use. Refer to the information provided in the product packaging and electronic Instructions for Use within the MYCITE APP.

2.2 Administration Instructions

ABILIFY MYCITE

Administer ABILIFY MYCITE orally with or without food *[see Clinical Pharmacology (12.3)]*. Swallow tablets whole; do not divide, crush, or chew.

MYCITE Patch

Apply the MYCITE Patch only when instructed by the app to the left side of the body just above the lower edge of the rib cage. Do not place the MYCITE Patch in areas where the skin is scraped, cracked, inflamed, or irritated, or in a location that overlaps the area of the most recently removed patch. Instruct patients to keep the patch on when showering, swimming, or exercising. The MYCITE Patch should be changed weekly or sooner as needed. The app will prompt patient to change the patch and will direct patient to apply and remove the patch correctly. Patients undergoing an MRI need to remove their patch and replace with a new one as soon as possible. If there is skin irritation, instruct patients to remove the patch.

2.3 Dosage in Schizophrenia

The recommended starting and target dosage for ABILIFY MYCITE in adults with schizophrenia is 10 or 15 mg daily. Dosage increases should generally not be made before 2 weeks *[see Clinical Pharmacology (12.3)]*. The maximum recommended dosage is 30 mg daily; however, doses above 15 mg daily have shown no additional clinically meaningful benefit.

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 co-administered drug is withdrawn from the combination therapy, ABILIFY MYCITE dosage should then be adjusted to its original level. When the co-administered 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

DOCKET ALARM

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