

MEDICATION GUIDE
ABILIFY MYCITE® (a BIL ĭ fi - Mi SIHYT)
(aripiprazole tablets with sensor), for oral use

Important:

- **If you are taking ABILIFY MYCITE with other medicines for treatment of major depressive disorder (MDD), you should also read the Medication Guides or Patient Information that comes with the other medicines.**
- **The ABILIFY MYCITE System has 4 parts:**
 - Aripiprazole tablet with an Ingestible Event Marker (IEM) sensor inside it (ABILIFY MYCITE).
 - MYCITE Patch (wearable sensor) that picks up (detects) the signal from the IEM sensor after you take the ABILIFY MYCITE tablet and sends the information to a smartphone.
 - MYCITE App, which is a smartphone application (app) that is used with a compatible smartphone to show information about when you take your ABILIFY MYCITE tablet.
 - Web-based portal for healthcare providers and caregivers.
- **Download the MYCITE App before using the ABILIFY MYCITE System. Always follow the instructions provided within the MYCITE App when using the ABILIFY MYCITE System.**
- **Your healthcare provider should show you how to use the ABILIFY MYCITE System before you use it for the first time.**

What is the most important information I should know about ABILIFY MYCITE?

ABILIFY MYCITE may cause serious side effects, including:

- **Increased risk of death in elderly people with dementia-related psychosis.** Medicines like ABILIFY MYCITE can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY MYCITE is not approved for the treatment of people who have lost touch with reality (psychosis) due to confusion or memory loss (dementia).
- **Increased risk of suicidal thoughts or actions in children and young adults.** Antidepressant medicines may increase suicidal thoughts or actions in some children and young adults within the first few months of treatment and when the dose is changed. It is not known if ABILIFY MYCITE is safe and effective for use in children.
 - **How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?**
 - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
 - Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
 - Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

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 ABILIFY 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.

© 2020, Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan

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

12US22IBR0002