



Talking to your patients about the **ABILIFY MYCITE® System**

This conversation guide, including commonly asked questions, can help you educate your patients and familiarize them with the ABILIFY MYCITE System.

Please see [FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**.

Not a real patient.





Introducing your patients to the ABILIFY MYCITE® System

To help your patients understand why they may be good candidates for the ABILIFY MYCITE System, share why you think the system may support their treatment goals. Explain how you will work together and use the data to personalize their care.¹

Then, using patient-friendly language, explain what the ABILIFY MYCITE System does and how it works.

The impact of the ABILIFY MYCITE System on treatment adherence has not been demonstrated. Some factors, such as connectivity, transmitter malfunction, or device availability, may impact the consistency and reliability of data detection, collection and transmission. Only functions related to tracking drug ingestion have been evaluated or approved by FDA.

Please see [IMPORTANT SAFETY INFORMATION](#) on page 6.

INDICATIONS

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

- Treatment of schizophrenia
- Treatment of bipolar I disorder as monotherapy and as adjunct to lithium or valproate for:
 - Acute treatment of manic and mixed episodes
 - Maintenance treatment
- Adjunctive treatment of major depressive disorder

Limitations of Use: ABILIFY MYCITE has not been shown to improve patient compliance or for use in modifying aripiprazole dosage. It should not be used in "real-time" or during an emergency, because detection may be delayed or not occur.

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

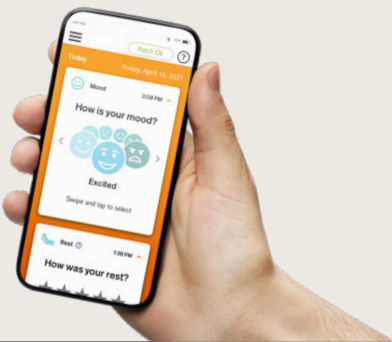
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death (1.6 to 1.7 times) compared to placebo-treated patients. ABILIFY MYCITE is not approved for the treatment of patients with dementia-related psychosis.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults. Those on antidepressant therapy should be monitored closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber. The safety and effectiveness of ABILIFY MYCITE have not been established in pediatric patients.


AbilifyMyCite®
(aripiprazole tablets with sensor)
2, 5, 10, 15, 20, 30 mg

Start by explaining the “why” behind the ABILIFY MYCITE® System



WHAT YOU NEED TO KNOW

- 1

It’s important that patients understand that this system is a tool for *them*. You’re recommending it because they’re someone who wants to do better with their treatment but might need a little help²

They can use the system to keep track of their personal medication management—along with information about their activity, rest, and self-reported rest quality and mood—so they can be more mindful of their medication-taking habits and better understand their own mental health treatment.¹
- 2

The ABILIFY MYCITE System is something you and your patients can use together to discuss how their treatment is going¹

Instead of having to remember everything that happened since their last visit, you and your patients will be able to view the same information when they come in for an appointment. This gives you a more holistic view, which can help you develop new, actionable insights.^{1,5}
- 3

Your patients’ medication-taking data will automatically be shared with you through the system¹

Your patients can also choose to share these data with other members of their care team and with people in their support network, like family or friends.¹
- 4

Sharing information can help patients stay on top of their treatment plan¹

It also gives them a regular way to communicate how they are doing with the important people in their lives.¹

WHAT YOU CAN SAY

- “Remembering to take your pill every day can be hard—particularly if you’re going through changes or you lack a daily routine. The ABILIFY MYCITE System can help by automatically logging when you take your pill, so you and I can have a better understanding of how you are doing.”²⁻⁴

“The ABILIFY MYCITE System was designed to help you stay on top of how your treatment is going so you and I can see the same information about how you’re doing in between visits. You have the option of entering more information about your mood, how well you rested, and, if you did not take your pill, the reason why you didn’t. Based on that, we can see how you are doing, discuss what we learn, and see if there is anything we should do differently.”¹
- “You can share the information in your app with me and, only if you want to, other members of your healthcare team and your support network, like close family members and friends, to help you stay connected. You can change what information you want to share at any time.”¹

“Being able to get better insights into how you’re doing will help us discuss any concerns you might have with your condition or your treatment and then come up with the best strategies to move forward that are personalized just for you.”^{6,7}

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Patients should know that the ABILIFY MYCITE System is something you both can use to get a better sense of how they’re doing between visits.¹

Explaining how the ABILIFY MYCITE® System works to keep you and your patients in communication

FOR YOU

A conversation¹

Equipped with the data delivered to you by the ABILIFY MYCITE System, you, your patients, and their support network can have more informed conversations.

Help your patients understand that it's about having a more in-depth conversation with the information provided by the ABILIFY MYCITE System. You can make more personalized treatment decisions when you know more about how they are doing between visits.

MYCITE® Dashboard¹

An online portal for you, and other people chosen by your patients, to see their objective and patient-reported data.

You can be transparent with your patient by letting them know that their data is set to be automatically shared with whomever they decide to connect with on the app. They can change this in their system settings later and stop sharing at any time.

FOR YOUR PATIENTS

ABILIFY MYCITE® (aripiprazole tablets with sensor)¹

After it is swallowed, the integrated technology in the smart pill sends a tiny signal to the MYCITE® Patch.

Remind patients that most ingestions will be detected within 30 minutes, but it may take up to two hours to detect the ingestion of the pill, and sometimes, it might not be detected. If this happens, patients should be told to not repeat the dose.

Remember to speak with your patients regarding the Important Safety Information associated with the aripiprazole component of ABILIFY MYCITE, especially those patients who are new to treatment.

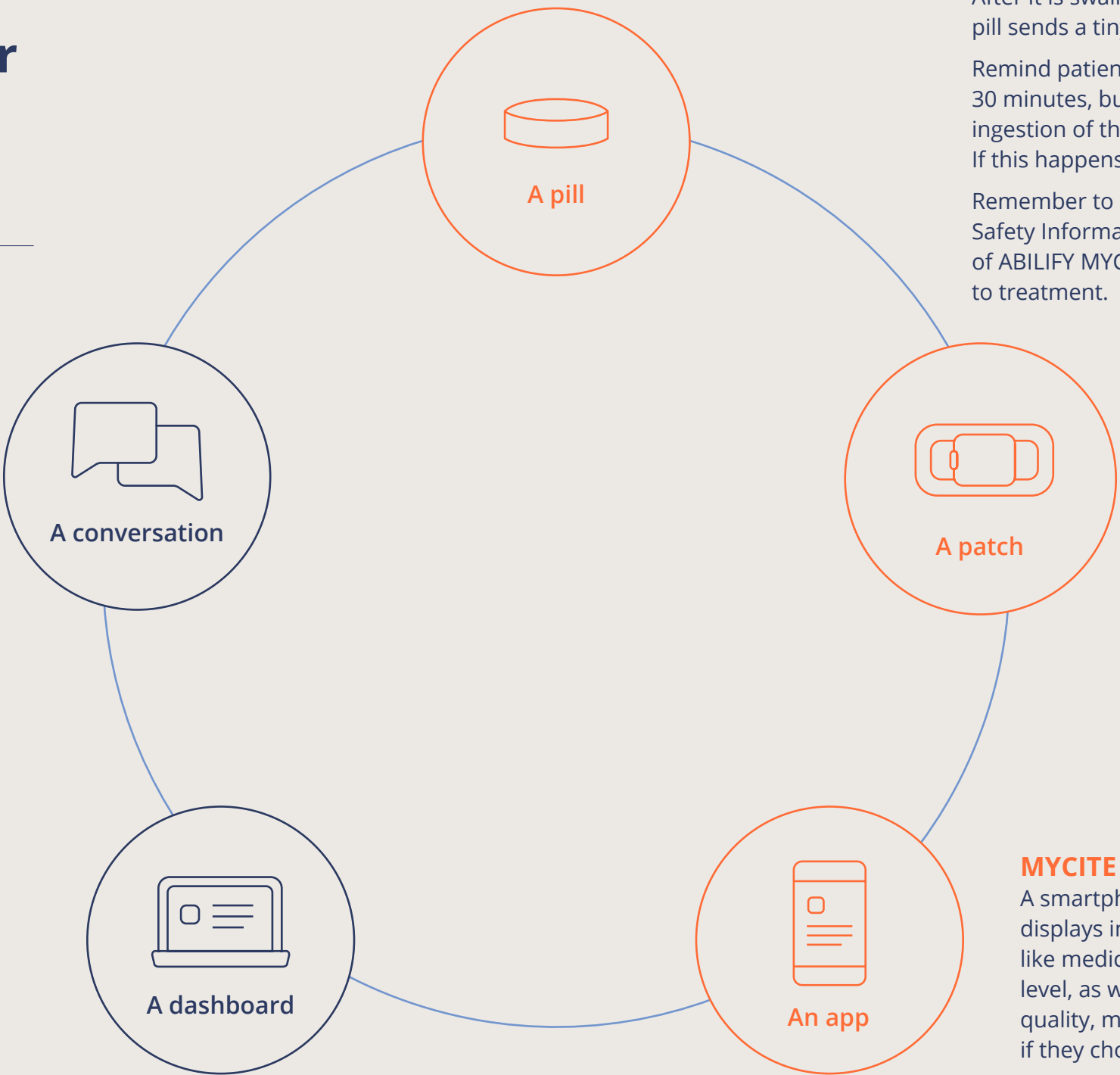
MYCITE Patch

A nonmedicated, wearable sensor made up of two parts: a reusable data pod and a weekly disposable adhesive strip that holds the pod in place. The pod contains a slim sensor that automatically logs when your patient takes their medication, as well as specific physiological data, such as activity and rest. Data are sent via Bluetooth®* to the MYCITE® App.

*Bluetooth is a registered trademark of Bluetooth SIG, Inc.

MYCITE App

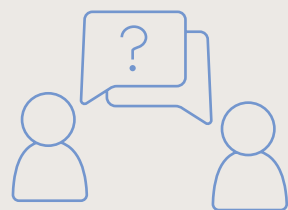
A smartphone application that receives and displays information from the Bluetooth patch, like medication-taking data and daily activity level, as well as the option to report their rest quality, mood, and reason for missing a dose, if they choose.



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Answer their commonly asked questions



Once you’ve introduced the ABILIFY MYCITE® System to your patients, they may have some questions. Here are some potential questions your patients may ask along with example answers.

Q: What is it like to take the pill?

A: ABILIFY MYCITE® (aripiprazole tablets with sensor) looks like other pills you may have taken before, and is similar in size. You can take ABILIFY MYCITE by mouth, with or without food. The sensor is completely covered by the tablet and does not change the size or texture of the pill. It is made up of natural ingredients found in most diets and leaves the body as waste. It is not possible to “feel” the sensor or the signal it sends. Do not crush, divide, or chew your ABILIFY MYCITE since that could damage the sensor or prevent it from functioning properly. There were no reported side effects related to the sensor or the signal.³

Q: How big is the smart pill sensor?

A: The sensor is the size of a grain of sand, so it does not impact the size of your medication.

Q: How big is the MYCITE® Patch?

A: The adhesive strip of the MYCITE Patch is about the size of a large adhesive bandage (about 2” x 4.25”), while the pod, attached in the center, is about the size of a small watch face.

Q: Who can see my information?

A: How you share your data always starts with you. As your healthcare provider, I will be able to see your data automatically when you finish setup. If you want, you can also share the daily data you see in the app with other members of your healthcare team, like your nurse or therapist, and anyone else you might want to view it—like close family members or friends. You can change what information you are sharing at any time.¹

The people with whom you choose to share your information will be able to view the data on the MYCITE® Dashboard, allowing them to get a better understanding of how you’re doing. In order to consent to sharing your information through the system, you will be asked to review and accept the Patient Terms of Use and Privacy Notice and Patient Authorization & Consent for the ABILIFY MYCITE System.

Q: How is my information seen by the people I share it with?

A: In addition to me, your healthcare provider, any other people you choose to invite will be able to view your information through the MYCITE Dashboard, which is a secure, online portal. Your data are encrypted and stored securely in the cloud to protect your privacy.¹

Q: How do I start using the ABILIFY MYCITE System?

A: First, your prescription will be sent to a specialty pharmacy. Once your prescription is approved to ship, the specialty pharmacy will send it here, or if we’re both comfortable, to your house. If you decide to ship it to our office, we will help set you up with the system and give you an overview of what’s in the ABILIFY MYCITE® Starter Kit. The kit includes your medicine, MYCITE Patches (1 reusable data pod and 7 disposable adhesive strips), and instructions on how to download the app and set up the system. If you decide to set up at home, you can call a dedicated nurse, or Patient Education Liaison (PEL), to walk you through the process.

Q: What is the cost of a prescription? Am I covered?

A: The cost of your prescription may depend on your health insurance. If you have a commercial plan (any plan that is not sponsored by a government program), you may pay as little as \$5 per month. Under most Medicaid plans, an ABILIFY MYCITE Starter Kit is covered after our office submits your prescription. You can work with our office and the specialty pharmacy to confirm coverage under our state’s Medicaid plan. If you are covered under Medicare and qualify for Low Income Subsidy (LIS), copays for brand-name products are \$9.20/month or less.^{8*}

Q: Who can I contact if I have any issues with the ABILIFY MYCITE System?

A: If you need technical help, the MYCITE® Team is there to answer any questions about the system. You can call the team at 844-MYCITE-4 (844-692-4834), 8 AM to 8 PM eastern time, Monday through Friday. Once we start the prescription process, you can also connect with a dedicated nurse, or PEL, who you can reach out to directly for personalized support throughout your treatment. You can enroll at 1-855-242-7787 8 AM to 8 PM eastern time, Monday through Friday, excluding holidays.



Find answers to other popular questions on [ABILIFYMYCITEhcp.com/resources-support](https://www.abilifymycitehcp.com/resources-support).

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*Offer not valid under Medicare, Medicaid, or other federal or state program. Further conditions apply. Contact the specialty pharmacy for more information.
[†]Verified October 30, 2020.

IMPORTANT SAFETY INFORMATION for ABILIFY MYCITE® (aripiprazole tablets with sensor)

WARNING: 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 (1.6 to 1.7 times) compared to placebo-treated patients. ABILIFY MYCITE is not approved for the treatment of patients with dementia-related psychosis.

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults. Those on antidepressant therapy should be monitored closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber. The safety and effectiveness of ABILIFY MYCITE have not been established in pediatric patients.

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

Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia-Related Psychosis: 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 aripiprazole.

Neuroleptic Malignant Syndrome (NMS): NMS is a potentially fatal symptom complex reported in association with administration of antipsychotic drugs, including ABILIFY MYCITE. 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 MYCITE, 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 in total cumulative dose of antipsychotic drugs. TD can develop after a relatively brief treatment period, even at low doses, or after discontinuation. If antipsychotic treatment is withdrawn, TD may remit, partially or completely. Prescribing should be consistent with the need to minimize TD.

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 ABILIFY MYCITE if such urges develop.

Orthostatic Hypotension: ABILIFY MYCITE 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.

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 MYCITE at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

Seizures: ABILIFY MYCITE 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 MYCITE may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery, including automobiles, until they are certain ABILIFY MYCITE does not affect them adversely.

Body Temperature Regulation: Use ABILIFY MYCITE 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 ABILIFY MYCITE. Use caution in patients at risk for aspiration pneumonia.

Dosage Adjustments and Cytochrome P450 Considerations: For patients with schizophrenia and bipolar I disorder taking ABILIFY MYCITE who are:

- Known CYP2D6 poor metabolizers, administer half the recommended dose
- Known CYP2D6 poor metabolizers taking concomitant strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin), administer a quarter the recommended dose.
- Taking strong CYP2D6 (e.g., quinidine, fluoxetine, paroxetine) or CYP3A4 inhibitors, administer half the recommended dose.
- Taking strong CYP2D6 and CYP3A4 inhibitors, administer a quarter the recommended dose. When co-administered drug is withdrawn, adjust ABILIFY MYCITE dosage to its original level.
- Taking strong CYP3A4 inducers (e.g., carbamazepine, rifampin), double recommended dose over 1 to 2 weeks. When co-administered drug is withdrawn, reduce ABILIFY MYCITE dosage to original level over 1 to 2 weeks.

Commonly Observed Adverse Reactions (incidence ≥5% and at least twice that for placebo) in adult patients:

- 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
- Major depressive disorder (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision

Dystonia: Symptoms of dystonia may occur in susceptible individuals during the first days of treatment and at low doses.

Skin Irritation for MYCITE Patch: Symptoms of skin irritation localized at the site of the MYCITE Patch may occur. In clinical studies, 12.4% of patients (n=61) experienced skin rashes at the site of patch placement.

Pregnancy: Neonates exposed to antipsychotic drugs, including ABILIFY MYCITE, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms. Consider the benefits and risks of ABILIFY MYCITE and possible risks to the fetus when prescribing ABILIFY MYCITE to a pregnant woman. Advise pregnant women of potential fetal risk. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ABILIFY MYCITE during pregnancy. For more information contact the National Pregnancy Registry for Atypical Antipsychotics at 1-866-961-2388 or visit <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>.

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

Help patients play a more active role in their treatment with the ABILIFY MYCITE® System¹

The ABILIFY MYCITE System is the only system that gives you objective medication ingestion and physiological data, as well as patient-reported data, to help inform treatment plans and encourage communication.

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Not a real patient.

The ABILIFY MYCITE System was designed with the privacy of patients' personal information in mind. Only those chosen by the patient may view patient information, and, at any time, the patients may change what information they want to share. For more information about the system's privacy requirements, please review the ABILIFY MYCITE System Terms of Use, Privacy Notice, and Authorization & Consent [here](#).

References: **1.** Otsuka and Proteus® announce the first U.S. FDA approval of a digital medicine system: ABILIFY MYCITE® (aripiprazole tablets with sensor). News release. Otsuka America Pharmaceutical, Inc. November 14, 2017. Accessed March 9, 2021. <https://www.otsuka-us.com/discover/articles-1075> **2.** Hatch A, Docherty JP, Carpenter D, Ross R, Weiden PJ. Expert consensus survey on medication adherence in psychiatric patients and use of a digital medicine system. *J Clin Psychiatry*. 2017;78(7):e803-e812. doi:10.4088/JCP.16m11252 **3.** Hafezi H, Robertson TL, Moon GD, Au-Yeung KY, Zdeblick MJ, Savage GM. An ingestible sensor for measuring medication adherence. *IEEE Trans Biomed Eng*. 2015;62(1):99-109. doi:10.1109/TBME.2014.2341272 **4.** Peters-Strickland T, Pestreich L, Hatch A, et al. Usability of a novel digital medicine system in adults with schizophrenia treated with sensor-embedded tablets of aripiprazole. *Neuropsychiatr Dis Treat*. 2016;12:2587-2594. doi:10.2147/NDT.S116029 **5.** Shafrin J, May SG, Shrestha A, et al. Access to credible information on schizophrenia patients' medication adherence by prescribers can change their treatment strategies: evidence from an online survey of providers. *Patient Prefer Adherence*. 2017;11:1071-1081. doi:10.2147/PPA.S135957 **6.** Chakrabarti S. What's in a name? Compliance, adherence and concordance in chronic psychiatric disorders. *World J Psychiatry*. 2014;4(2):30-36. doi:10.5498/wjp.v4.i2.30 **7.** Gelenberg AJ, Freeman MP, Markowitz JC, et al. Practice Guideline for the Treatment of Patients With Major Depressive Disorder. 3rd ed. American Psychiatric Association Publishing; 2010. Accessed March 9, 2021. https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf **8.** US Dept of Health & Human Services. Centers for Medicare & Medicaid Services. 2021 resource and cost-sharing limits for low-income subsidy (LIS). Accessed December 17, 2020. <https://www.cms.gov/files/document/lis-memo.pdf>