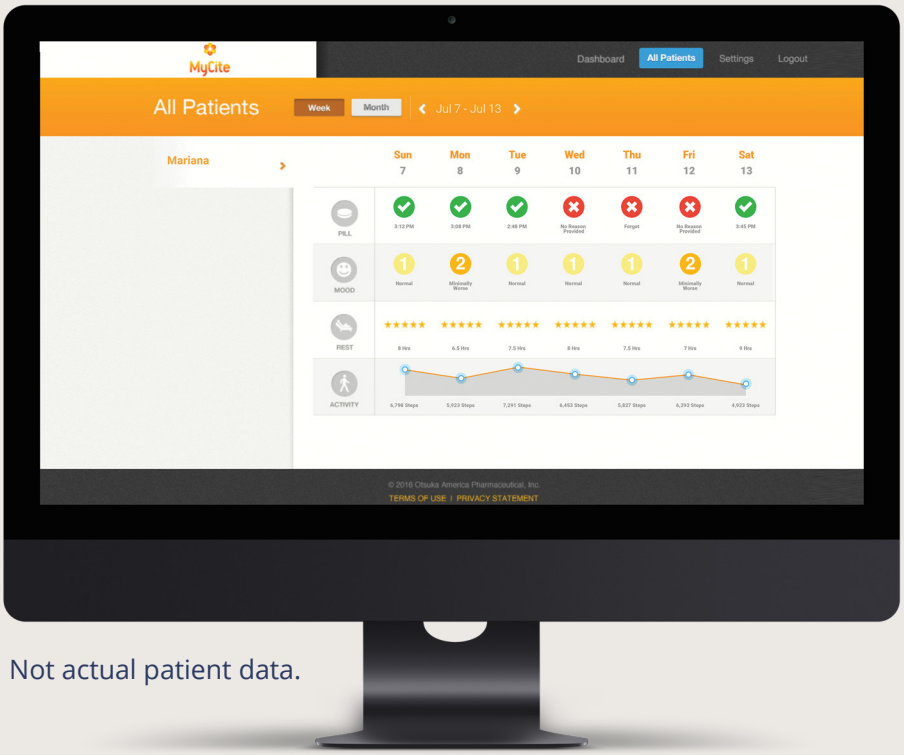
A look at the MYCITE® Dashboard

A component of the ABILIFY MYCITE® System



Not actual patient data.

The MYCITE Dashboard provides you with objective medication ingestion and patient-reported data over time

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 FULL PRESCRIBING INFORMATION, including **BOXED WARNING**.

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

The MYCITE® Dashboard

The MYCITE Dashboard uses robust data captured by the ABILIFY MYCITE® System to provide you with a more complete view of your adult patients

With the MYCITE Dashboard, you can review a summary of:

Objective medication ingestion data

Date and time of ingestion of ABILIFY MYCITE® (aripiprazole tablets with sensor)

Objective physiological data

Activity

Steps taken and miles walked every 24 hours

Rest

Extended periods of time when a patient's body is resting in a flat position up to an angle of 30°

Patient-reported data

Mood

Rest quality

Self-reported data, including mood, based on a 7-point visual scale, and quality of rest, based on a 5-point visual scale

Reason for a missed dose

Self-reported reasons for missing a dose, such as:

- I didn't feel like it
- I forgot
- I couldn't
- I took it after midnight
- I took my tablet but it did not register on the app

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.

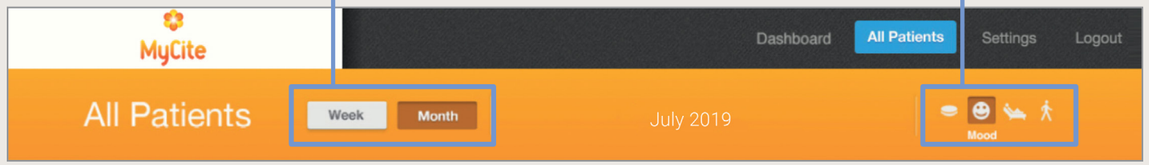
Navigating the MYCITE Dashboard

The easy-to-use dashboard allows you to quickly find the information you need

Switch between weekly and monthly views.

In the **monthly view**, switch between objective physiological data and patient-reported data.

The **weekly view** provides a comprehensive look at the patient's information by showing ingestion, mood, rest, and activity all at once.



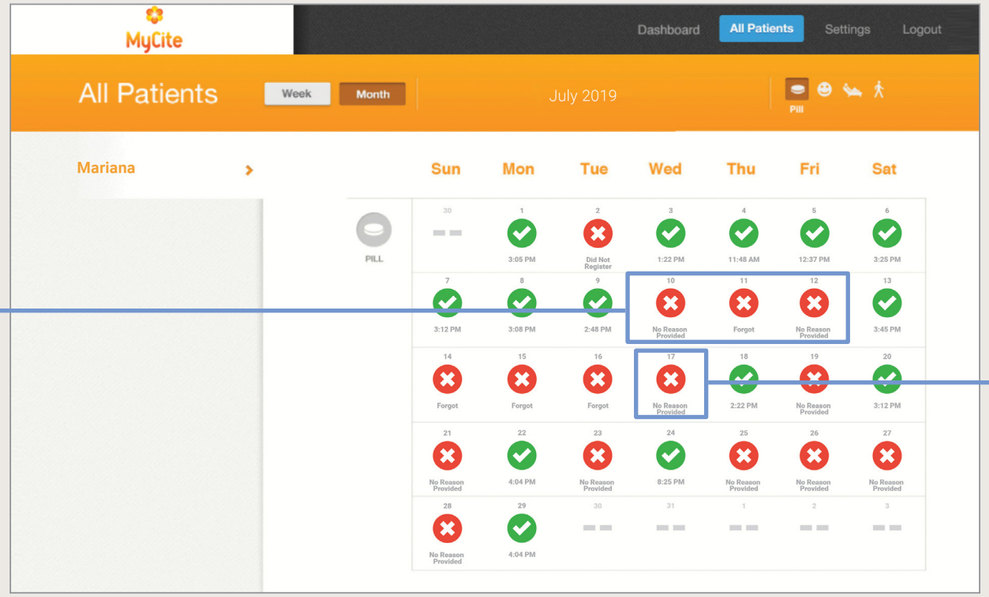
On the next few pages, you'll see what the data for a patient might look like.

Please see IMPORTANT SAFETY INFORMATION here.

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

Monthly view of ingestion

The monthly ingestion view provides valuable insight into your patient's medication-taking patterns in between visits to your office



A green check mark means the system detected ingestion.

A red X means the system did not detect ingestion.

Reviewing the patient's data, it looks like she had issues with taking her medication as prescribed starting in the second week of the month.

Starting on July 17, she stopped giving a reason for missing her medication.

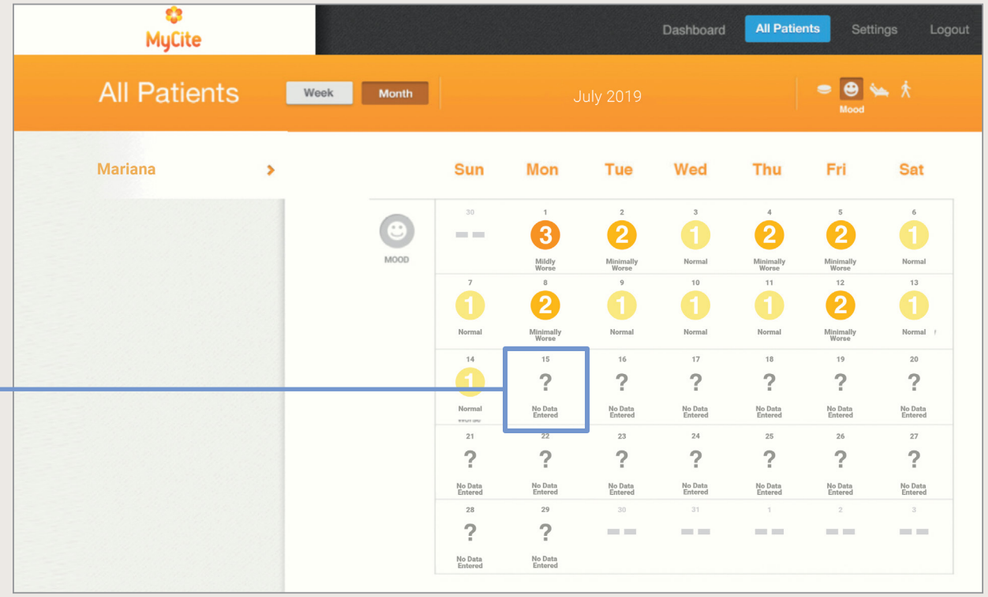
Although most ingestions will be detected within 30 minutes, it may take up to two hours to detect the ingestion of ABILIFY MYCITE® (aripiprazole tablets with sensor); in some cases, tablet ingestion may not be detected. If this occurs, patients should be told not to repeat the dose.

The ABILIFY MYCITE® System is not intended for real-time or emergency monitoring, because detection may be delayed or not occur.

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.

Monthly view of mood

Here is an example of patient-reported mood over the course of a month



As you can see, the patient stopped reporting her mood on July 15.

The patient's mood started to change right around the same time that she stopped taking her medication as prescribed.

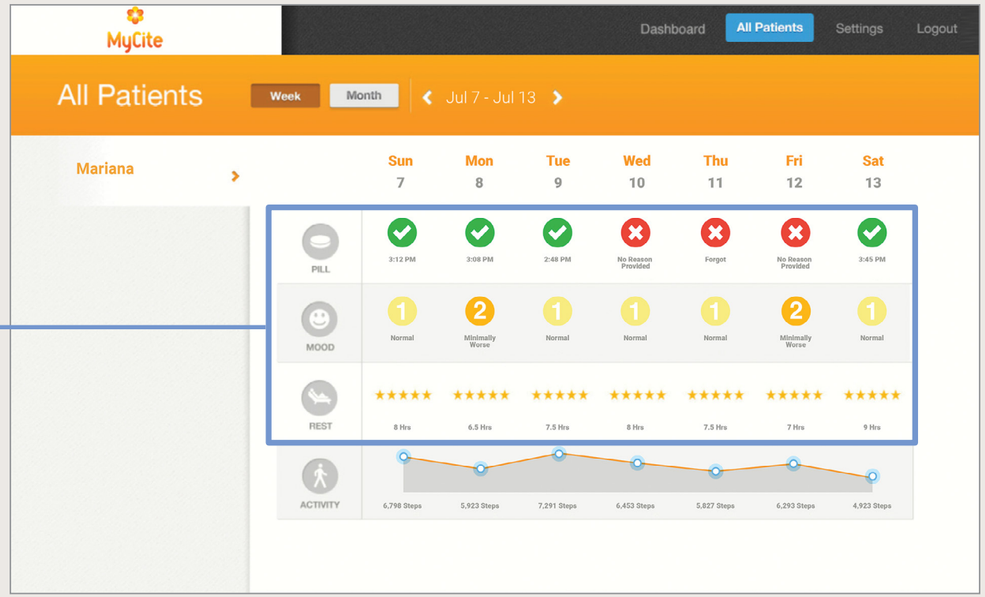
What actions might you take if you see these patterns in between a patient's visits?

Please see IMPORTANT SAFETY INFORMATION here.

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

The weekly view

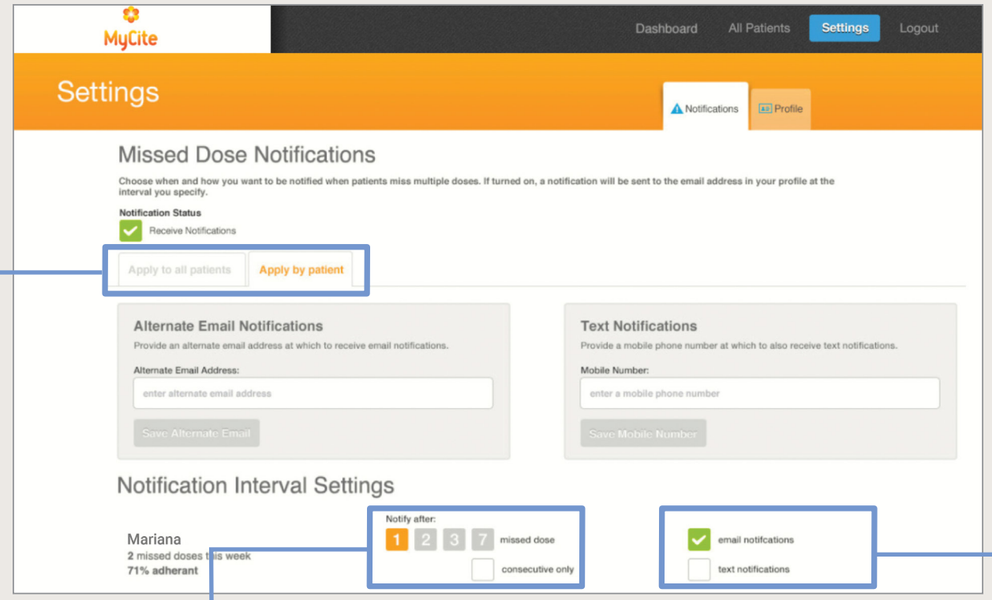
The weekly view allows you to review a summary of daily pill ingestion, rest, and activity levels, as well as patient-reported mood and rest-quality



This week of the patient's data shows that she took most of her medication, reported her mood, and had 6.5 to 9 hours of rest per day.

The MYCITE® Dashboard and missed doses

You can choose to set up email or text notifications for when your patients miss multiple or consecutive doses



For each patient, customize how often you want to receive notifications.

Choose email or text notifications.

Select certain patients or all patients.

See the reason your patients selected for missing a dose, like:

- I didn't feel like it
- I forgot
- I couldn't
- I took it after midnight
- I took my tablet but it did not register on the app

Knowing whether missed doses are intentional or unintentional can help guide the conversation with your patients and inform their treatment plans.[1]

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 here.

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

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

INDICATIONS

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 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.

IMPORTANT SAFETY INFORMATION

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

Continues on next page

Please see FULL PRESCRIBING INFORMATION, including **BOXED WARNING**.

IMPORTANT SAFETY INFORMATION for ABILIFY MYCITE® (aripiprazole tablets with sensor), cont'd

- 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**.

Support for healthcare providers

The MYCITE® Team can help you, your patients, and your office staff with:

- Setting up the ABILIFY MYCITE® System
- Questions and technical support
- Contacting the specialty pharmacy regarding a patient's prescription and refills

Call the MYCITE Team for more information at 844-MYCITE-3 (844-692-4833).

The MYCITE® Dashboard at a glance

The MYCITE Dashboard is used to view patient data, including information about medication ingestion, time spent resting, activity level, and patient-reported mood and rest quality.

With the MYCITE Dashboard, you can:

- View daily ingestion data at your discretion
- Review daily, weekly, or monthly activity and patient-reported rest and mood
- Set up notifications for patients' missed doses and see the reason your patients selected for missing a dose
- Align on patient status with other care team members

Only functions related to tracking drug ingestion have been evaluated or approved by FDA.

The ABILIFY MYCITE System is not intended for real-time or emergency monitoring, because detection may be delayed or not occur.

Reference: 1. 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.

Otsuka
Otsuka America Pharmaceutical, Inc.

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

April 2020 12US20EBP0049