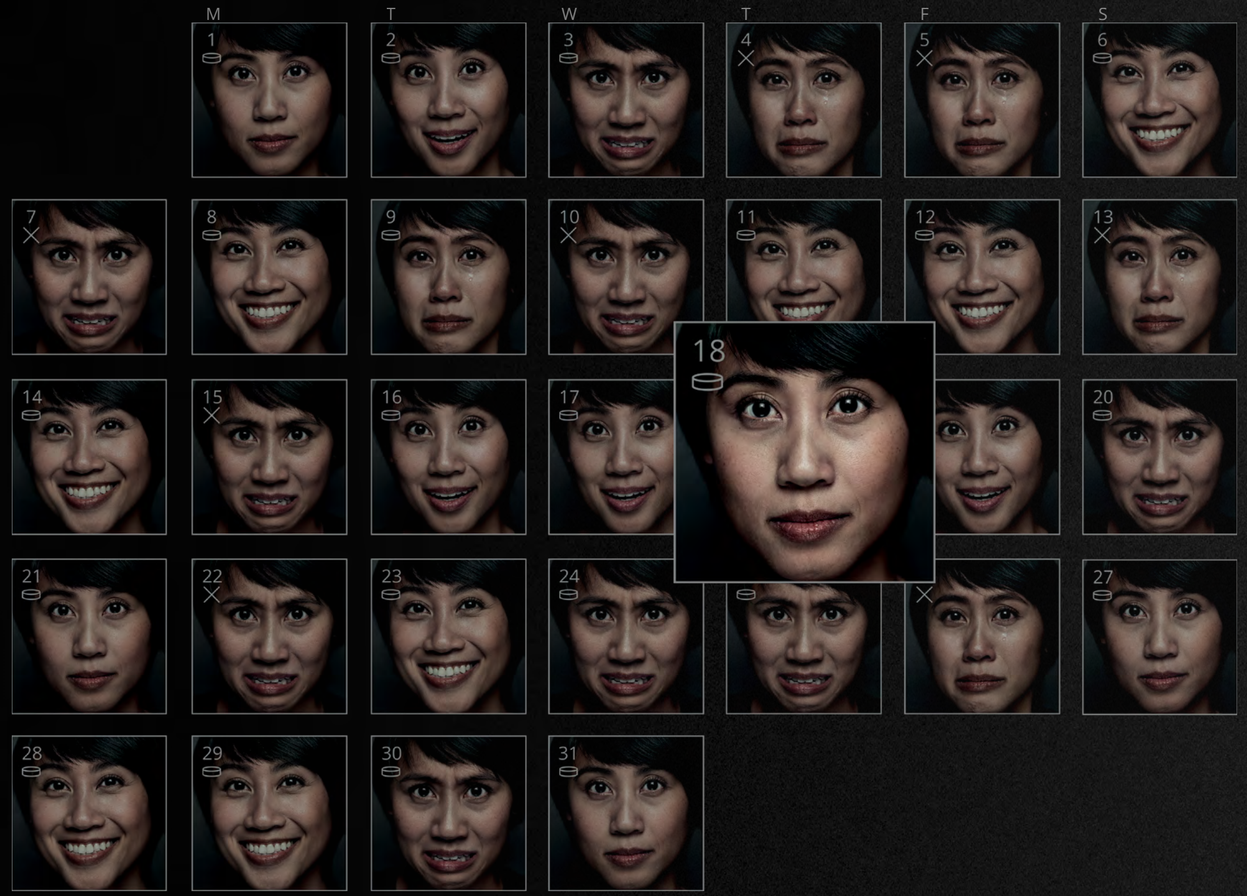


AbilifyMyCite®

(aripiprazole tablets with sensor)

2, 5, 10, 15, 20, 30 mg

An appointment may only show part of the story

Use data from the ABILIFY MYCITE® System to help spark a rich conversation.

Please see INDICATIONS and IMPORTANT SAFETY INFORMATION, including **BOXED WARNING**, on page 8.

Digital technology meets medicine in a smart pill

The ABILIFY MYCITE® System is the first FDA-approved digital medicine system. It captures robust objective and patient-reported data to help encourage communication between care teams and creates opportunities for more personalized treatment decisions[1]

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.

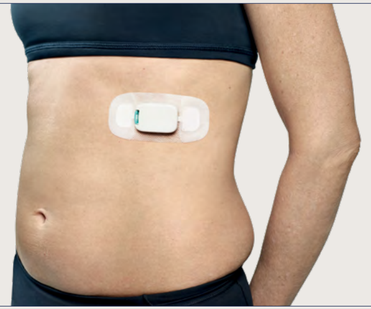
Please see IMPORTANT SAFETY INFORMATION on page 8.

Get more insight into what's happening every day

The ABILIFY MYCITE® System is the only system that delivers a combination of[1]:

OBJECTIVE DATA THROUGH THE MYCITE® PATCH

- Medication ingestion
- Activity (number of steps)
- Time spent resting



PATIENT-REPORTED DATA THROUGH THE MYCITE® APP

- Mood
- Rest quality
- Reason for a missed dose

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.

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

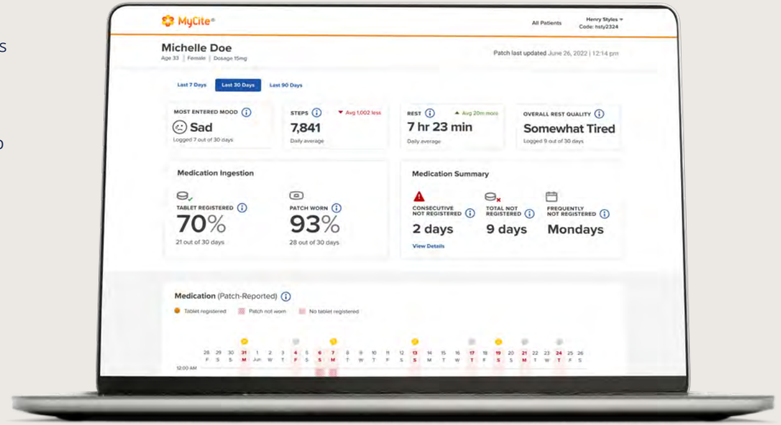
Please see IMPORTANT SAFETY INFORMATION on page 8.

The MYCITE® Dashboard: comprehensive data, all in one place

The ABILIFY MYCITE System captures patient-reported and objective data and presents them in the MYCITE Dashboard, providing you with a more complete view of your patients

With the MYCITE Dashboard, you can[1,2]:

- Get insight into medication-taking patterns
- See snapshot views of patient medication ingestion and other daily data
- Review daily data with your patient to help support their treatment plan



Illustrative data. Not from a real patient.

Reviewing patient-reported and objective data from the MYCITE Dashboard could help foster a more open dialogue between you and your patient.[2]

Abilify MyCite®
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2, 5, 10, 15, 20, 30 mg

Not a real patient.

What does the ABILIFY MYCITE® System offer you?

Visibility into your patients' medication ingestion patterns and other data may help you[2-4]:

IDENTIFY
factors contributing to nonadherence

ASSESS
treatment response, if adherent

PERSONALIZE
treatment strategies

STRENGTHEN
the therapeutic alliance

FOSTER
a more open dialogue

ENGAGE
and empower patients

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Important Warning and Precaution Regarding 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.

Please see IMPORTANT SAFETY INFORMATION on page 8.

Abilify MyCite®
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What can the ABILIFY MYCITE® System offer your patients?

By seeing their daily data, your patients have the opportunity to[1,5]:

BE PROACTIVE
in managing their mental health condition and reaching their treatment goals

BETTER UNDERSTAND
their treatment, see if they're taking their medication, and have greater insight into their medication ingestion patterns, mood, activity level, and rest

SHARE THEIR INFORMATION with their care team and support network so patients:

- Don't have to remember everything that has happened between appointments
- Stay connected throughout their treatment

The ABILIFY MYCITE System gives patients more ways to connect to their care team and support network. When everyone is working with the same information, it can help reduce uncertainty and foster trust.[1,2]

Important Warning and Precaution Regarding Neuroleptic Malignant Syndrome (NMS): NMS is a potentially fatal symptom complex reported in association with administration of antipsychotic drugs, including ABILIFY MYCITE® (aripiprazole tablets with sensor). 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.

Please see IMPORTANT SAFETY INFORMATION on page 8.

Not a real patient.

Is the ABILIFY MYCITE® System right for your patients?

Consider your patients who are[1,2,5]:

APPROPRIATE

Adult patients within the indicated population for ABILIFY MYCITE® (aripiprazole tablets with sensor)

FUTURE FOCUSED

Patients who want to move forward or are going through a transitional time in their lives, like changing care settings, or starting something new, like a job or a relationship

INVOLVED IN THEIR TREATMENT

Patients who are engaged and want to be more involved in their treatment

TECH EQUIPPED

Patients who are smartphone users, feel comfortable using apps, and have access to a reliable internet connection

The system may be particularly useful for managing patients who are[2,6]:

- Recently diagnosed or discharged from the hospital
- Changing their living situation
- Lacking a daily routine
- Experiencing an increase in symptoms and/or side effects after being previously stable

See if your patient is appropriate for the ABILIFY MYCITE System at ABILIFYMYCITEhcp.com/patient.

Important Warning and Precaution Regarding 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.

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AbilifyMyCite®
(aripiprazole tablets with sensor)
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Meet what makes up the ABILIFY MYCITE® System

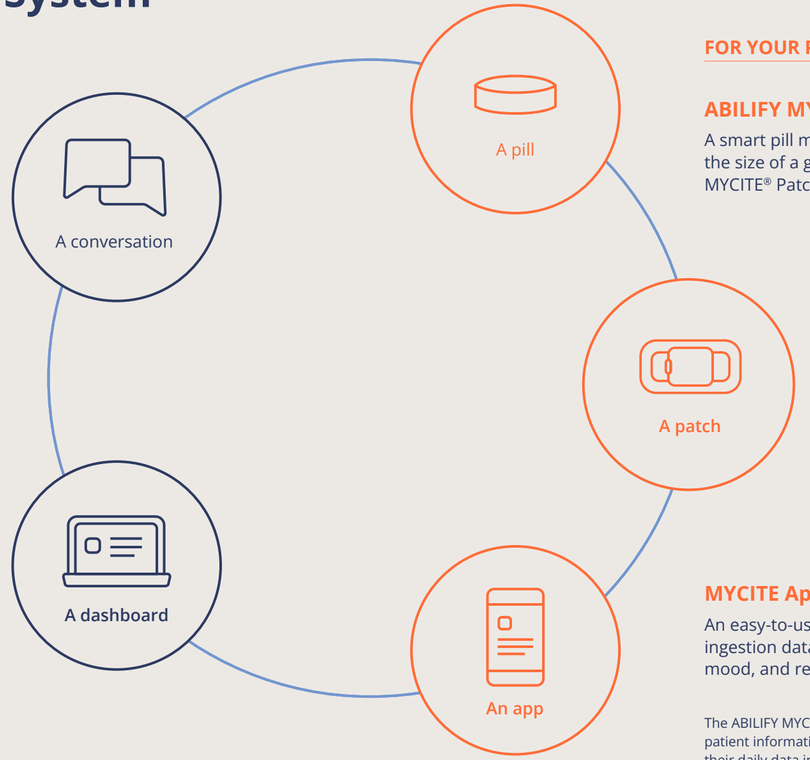
FOR YOU

A conversation

Equipped with the data delivered to you by the ABILIFY MYCITE System, you, your patients, and their care team and support network can have more-informed conversations about your patients' mental health and treatment plan.[1]

MYCITE® Dashboard

An online portal for healthcare providers and the patient's support network that displays weekly and monthly views of medication ingestion, physiological data, and patient-reported data over time.



FOR YOUR PATIENT

ABILIFY MYCITE® (aripiprazole tablets with sensor)

A smart pill manufactured with integrated technology the size of a grain of sand that sends a signal to the MYCITE® Patch after ingestion.[1]

MYCITE Patch

A nonmedicated, wearable sensor made up of 2 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

An easy-to-use smartphone app for the patient to review their ingestion data and daily activity level, and to report their rest quality, mood, and reason for missing a dose.

The ABILIFY MYCITE System encrypts all data and stores them securely in the cloud to protect patient information. How patients share their information is up to them. Patients can share their daily data in their app with their healthcare provider, care team, or anyone else they would want to know—like close family members or friends. Once connected, healthcare providers and the support network will see patient daily data (ingestion, mood, activity, rest) by default. Patients can change what information they want to share at any time.[1]

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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

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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/.

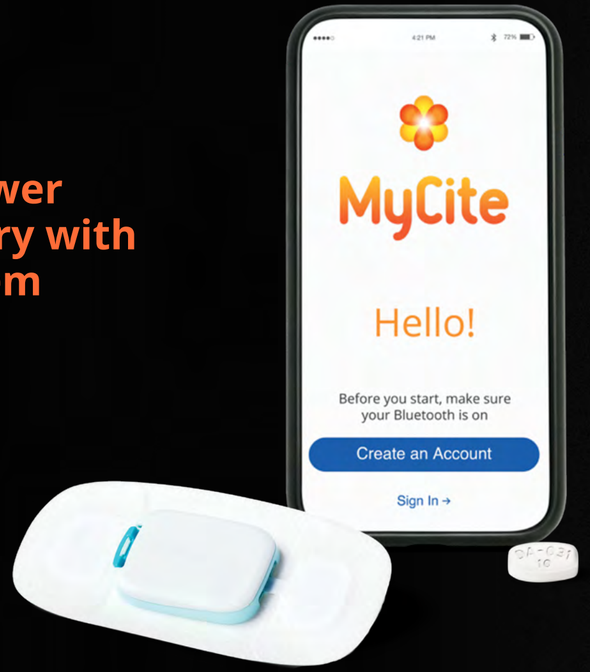
Lactation: Aripiprazole is present in human breast milk; however, there are insufficient data to assess the amount in human milk, effects on the breastfed infant, or effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical 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**.

Give your patients the power to share more of their story with the ABILIFY MYCITE® System

Don't wait to learn more.
Visit ABILIFYMYCITEhcp.com and start the conversation with your patients.



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

The privacy of the patients' personal information shared through the ABILIFY MYCITE System is important. Only those chosen by the patient may view their information, and the patient may choose to stop sharing their information at any time.

For more information about the system's privacy requirements for you, your patients, and their family & friends, please review the ABILIFY MYCITE System Terms of Use, Privacy Notice, and Authorization & Consent here.

References: 1. News release. Otsuka America Pharmaceutical, Inc. November 14, 2017. Accessed May 25, 2022. https://www.otsuka-us.com/discover/articles-1075 **2.** Hatch et al. *J Clin Psychiatry*. 2017;78(7):e803-e812. doi:10.4088/JCP.16m11252 **3.** Shafrin et al. *Patient Prefer Adherence*. 2017;11:1071-1081. doi:10.2147/PPA.S135957 **4.** Elenko et al. *Nat Biotechnol*. 2015;33(5):456-461. doi:10.1038/nbt.3222 **5.** Sawesi et al. *JMIR Med Inform*. 2016;4(1):e1. doi:10.2196/medinform.4514 **6.** Rossom et al. *Depress Anxiety*. 2016;33(8):765-774. doi:10.1002/da.22532

Otsuka
Otsuka America Pharmaceutical, Inc.

 July 2022 12US22EBP0034

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