


Abilify Asimtufii[®]
(aripiprazole) extended release
suspension for injection 960mg


Abilify Maintena[®]
(aripiprazole) for extended release injectable suspension 400mg

Could a
**long-lasting
treatment***
for **bipolar I disorder**
be right for you?



**ABILIFY ASIMTUFII[®] (aripiprazole) and ABILIFY MAINTENA[®] (aripiprazole)
are each used alone as bipolar I disorder maintenance treatments for adults.**

*Based on a 1-year study of once-monthly ABILIFY MAINTENA, people treated with ABILIFY MAINTENA had no mood episodes for significantly longer than those on placebo. In a separate study of ABILIFY ASIMTUFII and ABILIFY MAINTENA, both medicines resulted in similar levels of aripiprazole in the body, suggesting a similar level of symptom control. Results may vary. Work with your healthcare provider to make sure you can tolerate aripiprazole prior to starting treatment.

INDICATIONS:

ABILIFY ASIMTUFII is a prescription medicine given by injection by a healthcare professional:

- for the treatment of schizophrenia in adults
- alone as maintenance treatment of bipolar I disorder in adults

ABILIFY MAINTENA is a prescription medicine given by injection by a healthcare professional:

- for the treatment of schizophrenia in adults
- alone as maintenance treatment of bipolar I disorder in adults

It is not known if ABILIFY ASIMTUFII or ABILIFY MAINTENA is safe and effective in children under 18 years of age.

SELECT IMPORTANT SAFETY INFORMATION:

Increased risk of death in elderly people with dementia-related psychosis. ABILIFY ASIMTUFII and ABILIFY MAINTENA increase the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY ASIMTUFII and ABILIFY MAINTENA are not for the treatment of people with dementia-related psychosis.

(Continued on next page)

Please read **IMPORTANT SAFETY INFORMATION** on pages 11-12.

Table of Contents

What is a long-acting injectable (LAI)?	<u>3</u>
A dosing schedule that meets your needs	<u>4</u>
Study results	<u>5</u>
Possible side effects	<u>6</u>
What to expect with your injections	<u>7</u>
Tips for getting started and staying on track	<u>8</u>
How you may be able to save	<u>9</u>
Support and resources	<u>10</u>
Important Safety Information	<u>11-12</u>

Find out if ABILIFY ASIMTUFII® (aripiprazole) or ABILIFY MAINTENA® (aripiprazole) could be your next step in treating bipolar I disorder.

SELECT IMPORTANT SAFETY INFORMATION

Do not receive ABILIFY ASIMTUFII or ABILIFY MAINTENA if you are allergic to aripiprazole or any of the ingredients in ABILIFY ASIMTUFII or ABILIFY MAINTENA.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 11-12.



What is a long-acting injectable (LAI)?

- A potential alternative to taking a daily pill
- An injection that is given by a healthcare provider
- Each dose delivers medicine over an extended period of time



How LAIs work

- LAIs are injections that use the same medicine that comes in a pill form
- The medicine is released in the body slowly over time, like sand in an hourglass
- LAIs are designed to provide you with the amount of medicine you need over an extended period

Taking
ABILIFY ASIMTUFII
could mean

1

injection
every
2 months

instead of 60 pills.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII® (aripiprazole) or ABILIFY MAINTENA® (aripiprazole) may cause serious side effects, including:

- **Increased risk of stroke** and ministroke has been reported in clinical studies with oral aripiprazole of elderly people with dementia-related psychosis and can lead to death.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 11-12.


AbilifyAsimtufii
(aripiprazole) extended release
suspension for injection


AbilifyMaintena
(aripiprazole) for extended release injectable suspension

A dosing schedule that meets your needs

ABILIFY ASIMTUFII® (aripiprazole) and ABILIFY MAINTENA® (aripiprazole) are long-acting injectables that may provide long-lasting symptom control* for bipolar I disorder. One dose could provide symptom control for up to 2 months.

- ABILIFY ASIMTUFII and ABILIFY MAINTENA both use the **same active ingredient, aripiprazole**, which was originally developed as an oral medication
- Oral aripiprazole has been used to treat over 2 million people with bipolar disorders†
- ABILIFY ASIMTUFII and ABILIFY MAINTENA are indicated for one type of bipolar disorder: **bipolar I disorder**

ONCE EVERY 2 MONTHS

ABILIFY ASIMTUFII may provide 2 months of bipolar I disorder symptom control* with each dose.



OR

ONCE MONTHLY

ABILIFY MAINTENA may provide 1 month of bipolar I disorder symptom control* with each dose.



Work with your doctor to decide which dosing schedule might be right for you.

*Based on a 1-year study of people treated with once-monthly ABILIFY MAINTENA, people treated with ABILIFY MAINTENA had no mood episodes for a significantly longer period of time than those on placebo. In a separate 8-month study of ABILIFY ASIMTUFII and ABILIFY MAINTENA in people with bipolar I disorder and schizophrenia, it was shown that both medicines resulted in similar levels of aripiprazole in the body, suggesting a similar level of symptom control. Results may vary.

†Based on the number of people who have received brand name or generic oral aripiprazole for bipolar disorders since 2015.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII or ABILIFY MAINTENA may cause serious side effects, including (continued):

- **Neuroleptic malignant syndrome (NMS), a serious condition that can lead to death.** Call your healthcare provider or go to the nearest emergency room right away if you have some or all of the following signs and symptoms of NMS: high fever, confusion, changes in pulse, heart rate, and blood pressure, stiff muscles, and increased sweating.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 11-12.



Study results

ABILIFY MAINTENA® (aripiprazole) and ABILIFY ASIMTUFII® (aripiprazole) are designed to help control bipolar I disorder symptoms without the need for a daily pill. See below to learn about the results of clinical studies for each of these LAIs.



Once-monthly ABILIFY MAINTENA was shown to give more time between mood episodes.



A 1-year study found that those who were treated with ABILIFY MAINTENA remained **mood episode-free significantly longer** than those who were not treated with ABILIFY MAINTENA.*



In this study, significantly fewer people (27%) had a mood episode return while on ABILIFY MAINTENA compared with those who were on placebo† (51%).

*This study of ABILIFY MAINTENA measured how well symptoms were controlled in 266 people with bipolar I disorder. The study measured the time to recurrence of mood episodes for adults living with bipolar I disorder. Individual results may vary.

†A substance that contains no medicine.



Once every-2-months ABILIFY ASIMTUFII was approved based on key studies of ABILIFY MAINTENA.

One of these was the 1-year study of ABILIFY MAINTENA shown above.



Another study† measured the amount of medicine in people and showed that the medicine in ABILIFY ASIMTUFII stayed at a similar level in the body for 2 months as the medicine in ABILIFY MAINTENA did for 1 month.

†This 8-month study included 81 people with bipolar I disorder and 185 people with schizophrenia. The study measured the similarity of concentrations of medicine (aripiprazole) between ABILIFY ASIMTUFII and ABILIFY MAINTENA after 28 days of treatment with ABILIFY ASIMTUFII and 56 days of treatment with ABILIFY MAINTENA.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII or ABILIFY MAINTENA may cause serious side effects, including (continued):

- **Uncontrolled body movements (tardive dyskinesia).** ABILIFY ASIMTUFII and ABILIFY MAINTENA 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 receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA. Tardive dyskinesia may also start after you stop receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 11-12.



Possible side effects

The side effects of ABILIFY MAINTENA® (aripiprazole) were evaluated in a 12-week study of 339 people living with schizophrenia. The safety profile of ABILIFY ASIMTUFII® (aripiprazole) is based on the safety profile of ABILIFY MAINTENA.

In the 12-week study, the most common side effects of ABILIFY MAINTENA were:



Weight gain



Inner sense of restlessness (feeling like you need to move)



Injection site pain



Sleepiness (sedation)

These are not all the possible side effects.

In the study, the most common side effects were defined as those that happened with an incidence equal to or more than 5% and at least twice that of those taking placebo.



In this study, **no one stopped treatment with ABILIFY MAINTENA** because of these 4 most common side effects.

Always discuss side effects you may have with your healthcare team.
Please read the [Important Safety Information](#) on pages 11-12.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII or ABILIFY MAINTENA may cause serious side effects, including (continued):

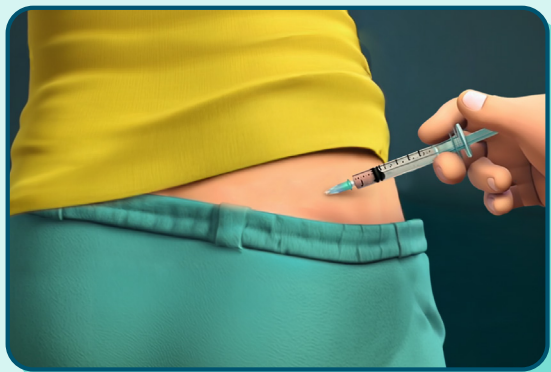
- Problems with your metabolism such as:

- » **High blood sugar (hyperglycemia) and diabetes:** Increases in blood sugar can happen in some people who are treated with ABILIFY ASIMTUFII or ABILIFY MAINTENA. 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 treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA, and during treatment.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 11-12.



What to expect with your injections



The ABILIFY ASIMTUFII® (aripiprazole) and ABILIFY MAINTENA® (aripiprazole) injections are given by a doctor, nurse, or pharmacist. Talk to your doctor to learn more about how you'll receive them.

ABILIFY ASIMTUFII is injected just below the waistline in the upper gluteal muscle. ABILIFY MAINTENA is injected into the upper gluteal muscle or the shoulder.

You may need to loosen a belt or a waistband, but there typically is no need to remove clothing.

What did people in a study say about pain?



Most people did not feel pain

In a study, about 8 out of 10 people receiving ABILIFY ASIMTUFII and 9 out of 10 people receiving ABILIFY MAINTENA **did not** report feeling injection site pain.



Pain was low

Those who said they felt pain rated their pain as **less than 4** on a scale from 0 to 100.



Pain lessened over time

Most people who said they felt injection site pain reported that the **pain lessened** with each injection.

Options for where to get your injections

You have options to receive your injection. Beyond your **doctor's office**, some **retail pharmacies** and **local care clinics** also give LAI injections.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII or ABILIFY MAINTENA may cause serious side effects, including (continued):

Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA:

- 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

Please read **IMPORTANT SAFETY INFORMATION** on pages 11-12.



Tips for getting started and staying on track

1

Before starting

- Talk to your doctor or nurse about other medications you're taking, including prescription and over-the-counter medicines
- Do not start or stop any medicines while taking these LAIs without talking to your doctor first

2

When starting

- Work with your doctor to decide the right time to start your LAI and the appropriate steps to transition from your current medication
- If you are taking an oral antipsychotic (including aripiprazole), your doctor may have you continue to take it for up to 2 weeks after your first LAI injection

3

After you've started

- Receiving every dose and sticking to your treatment schedule are important to help keep the level of medicine in your body consistent
- If you miss a dose, talk to your doctor about how and when to make up the missed dose

[Click here](#) for more information on how to transition from your current medication when you and your doctor decide you are ready.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII® (aripiprazole) or ABILIFY MAINTENA® (aripiprazole) may cause serious side effects, including (continued):

- **Unusual and uncontrollable (compulsive) urges.** Some people receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA have had unusual strong urges to gamble and gambling that cannot be controlled (compulsive gambling). Other compulsive urges include sexual urges, shopping, and eating or binge eating. If you or your family members notice that you are having unusual urges or behaviors, talk to your healthcare provider.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 11-12.





Pay as little as \$0 per dose with your Savings Card

With the Savings Card, you may be eligible to pay less for your prescription* of **ABILIFY ASIMTUFII® (aripiprazole)** or **ABILIFY MAINTENA® (aripiprazole)**.

ABILIFY ASIMTUFII

Eligible patients may pay as little as \$0 per fill with an annual maximum benefit of \$8,000 and a monthly maximum benefit of wholesale acquisition cost plus usual and customary pharmacy charges. Presumes only 1 prescription filled per 2 calendar months. Conditions apply.

ABILIFY MAINTENA

Eligible patients may pay as little as \$0 per fill with an annual maximum benefit of \$8,000 and a monthly maximum benefit of \$1,400. Presumes only 1 prescription filled per calendar month. Conditions apply.

Talk to your insurance provider to find out your actual cost.

[Click here](#) to see if you qualify to save on your prescription.

*[Click here](#) for conditions that may apply.

SELECT IMPORTANT SAFETY INFORMATION

ABILIFY ASIMTUFII or ABILIFY MAINTENA may cause serious side effects, including (continued):

- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 11-12.

ABILIFY ASIMTUFII® (aripiprazole) SAVINGS CARD

PAY AS LITTLE AS **\$0** PER FILL*

BIN# 610020
Group# 99994400
Member ID#


Abilify Asimtufii
(aripiprazole) extended release suspension

*Conditions apply. Please see Details and Eligibility for information.
Please read FULL PRESCRIBING INFORMATION, including **BOXED WARNING**, and MEDICATION GUIDE
October 2025 23US25EXC0077

ABILIFY MAINTENA® (aripiprazole) SAVINGS CARD

PAY AS LITTLE AS **\$0** PER FILL*

BIN# 610020
Group#
Member ID#


Abilify Maintena
(aripiprazole) extended release injectable suspension

*Conditions apply. Please see Details and Eligibility for information.
Please read FULL PRESCRIBING INFORMATION, including **BOXED WARNING**, and MEDICATION GUIDE
October 2025 23US25EXC0077


Abilify Asimtufii
(aripiprazole) extended release suspension for injection


Abilify Maintena
(aripiprazole) extended release injectable suspension

Support and resources

Having the right support can help you along your journey living with bipolar I disorder. Here are some organizations that may provide additional resources and support to help you stay on track.



Patient Advocate Foundation

Helps patients manage their care and provides financial aid to patients with chronic, life-threatening, and debilitating diseases.



National Institutes
of Health

National Institute of Mental Health

Supports and conducts research on mental illness and the underlying science of the brain and behavior.



Depression and Bipolar Support Alliance

Provides in-person and online peer support dedicated to improving the lives of people living with mood disorders.



Clubhouse
International
Creating Community:
Changing the World of Mental Health

Clubhouse International

Helps people living with mental illness around the world regain a respected place in society through work, education, wellness, and community.



National Alliance on Mental Illness

Provides advocacy educations, support, and public awareness to help those affected by mental illness.

The organizations listed are independent from Otsuka America Pharmaceutical, Inc. While Otsuka may provide financial support to some of these groups, their inclusion here is for informational purposes only. Otsuka does not endorse or recommend any specific organization, and patients are encouraged to consider all available resources and make independent decisions about their care and support needs.

[Click here for more useful tools and resources.](#)



Important Safety Information

INDICATIONS and IMPORTANT SAFETY INFORMATION for ABILIFY ASIMTUFII® (aripiprazole) and ABILIFY MAINTENA® (aripiprazole)

INDICATIONS:

ABILIFY ASIMTUFII is a prescription medicine given by injection by a healthcare professional:

- for the treatment of schizophrenia in adults
- alone as maintenance treatment of bipolar I disorder in adults

ABILIFY MAINTENA is a prescription medicine given by injection by a healthcare professional:

- for the treatment of schizophrenia in adults
- alone as maintenance treatment of bipolar I disorder in adults

It is not known if ABILIFY ASIMTUFII or ABILIFY MAINTENA is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION:

Increased risk of death in elderly people with dementia-related psychosis. ABILIFY ASIMTUFII and ABILIFY MAINTENA increase the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). ABILIFY ASIMTUFII and ABILIFY MAINTENA are not for the treatment of people with dementia-related psychosis.

Do not receive ABILIFY ASIMTUFII or ABILIFY MAINTENA if you are allergic to aripiprazole or any of the ingredients in ABILIFY ASIMTUFII or ABILIFY MAINTENA.

ABILIFY ASIMTUFII or ABILIFY MAINTENA may cause serious side effects, including:

- **Increased risk of stroke** and ministroke has been reported in clinical studies with oral aripiprazole of elderly people with dementia-related psychosis and 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 emergency room right away if you have some or all of the following signs and symptoms of NMS: high fever, confusion, changes in pulse, heart rate, and blood pressure, stiff muscles, and increased sweating.
- **Uncontrolled body movements (tardive dyskinesia).** ABILIFY ASIMTUFII and ABILIFY MAINTENA 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 receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA. Tardive dyskinesia may also start after you stop receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA.

• Problems with your metabolism such as:

- » **High blood sugar (hyperglycemia) and diabetes:** Increases in blood sugar can happen in some people who are treated with ABILIFY ASIMTUFII or ABILIFY MAINTENA. 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 treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA, and during treatment.

Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA:

- 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 during treatment.

- **Unusual and uncontrollable (compulsive) urges.** Some people receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA have had unusual strong urges to gamble and gambling that cannot be controlled (compulsive gambling). Other compulsive urges include sexual urges, shopping, and eating or binge eating. 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.** ABILIFY ASIMTUFII and ABILIFY MAINTENA may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position (orthostatic hypotension), and can slow your thinking and motor skills, which may lead to falls that can cause fractures or other injuries.
- **Low white blood cell count.** Your healthcare provider may do blood tests during the first few months of treatment.

(Continued on next page)



Important Safety Information (continued)

ABILIFY ASIMTUFII® (aripiprazole) or ABILIFY MAINTENA® (aripiprazole) may cause serious side effects, including (continued):

- **Seizures (convulsions)**
- **Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities. Do not** drive a car, operate machinery, or do other dangerous activities until you know how ABILIFY ASIMTUFII® or ABILIFY MAINTENA® affects you. ABILIFY ASIMTUFII or ABILIFY MAINTENA may make you feel drowsy and affect your judgement, thinking, or motor skills.
- **Problems controlling your body temperature so that you feel too warm. Do not** become too hot or dehydrated during treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA. **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.
- **Difficulty swallowing** that can cause food or liquid to get into your lungs.

Do not drink alcohol during treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA.

Before receiving ABILIFY ASIMTUFII or ABILIFY MAINTENA, tell your healthcare provider about all your medical conditions, including if you:

- have never taken aripiprazole before
- have or had diabetes or high blood sugar or a family history of diabetes or high blood sugar
- have or had high levels of total cholesterol, LDL cholesterol, or triglycerides, or low levels of HDL cholesterol
- have or had low or high blood pressure
- have or had heart problems or a stroke
- have or had a low white blood cell count
- have or had seizures (convulsions)
- have problems that may affect you receiving an injection in your buttocks (ABILIFY ASIMTUFII and ABILIFY MAINTENA) or arm (ABILIFY MAINTENA)
- are pregnant or plan to become pregnant. ABILIFY ASIMTUFII or ABILIFY MAINTENA may harm your unborn baby. If you become pregnant during treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA, talk to your healthcare provider about the risk to your unborn baby and about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or visit <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>

- are breastfeeding or plan to breastfeed. ABILIFY ASIMTUFII or ABILIFY MAINTENA can pass into your milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you receive ABILIFY ASIMTUFII or ABILIFY MAINTENA.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements.

ABILIFY ASIMTUFII or ABILIFY MAINTENA and other medicines may affect each other, causing possible serious side effects. Do not start or stop any medicines during treatment with ABILIFY ASIMTUFII or ABILIFY MAINTENA without talking to your healthcare provider first.

The most common side effects of ABILIFY ASIMTUFII or ABILIFY MAINTENA include: weight gain, restlessness or feeling like you need to move (akathisia), injection site pain, or sleepiness (sedation).

It is important to contact your healthcare provider if you experience prolonged, abnormal muscle spasms or contractions, which may be signs of a condition called dystonia.

These are not all the possible side effects of ABILIFY ASIMTUFII or ABILIFY MAINTENA.

If you have any questions about your health or medicines, talk to your healthcare provider.

You are encouraged to report side effects of ABILIFY ASIMTUFII and ABILIFY MAINTENA. Please 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**, for [ABILIFY ASIMTUFII](#) and [ABILIFY MAINTENA](#), and MEDICATION GUIDE for [ABILIFY ASIMTUFII](#) and [ABILIFY MAINTENA](#).





Talk to your doctor about ABILIFY ASIMTUFII® (aripiprazole) and ABILIFY MAINTENA® (aripiprazole)

It's important to talk with your doctor about your treatment.
But it's not always easy to start the conversation.



Here are some questions you could ask
your doctor at your next appointment:

Could an LAI help me control my
bipolar I disorder symptoms?

Are the side effects similar to my current treatment?

Which dosing schedule is right for me?



[Click here](#)
to create your
personalized Doctor
Discussion Guide.

Please read [IMPORTANT SAFETY INFORMATION](#) on pages 11-12.



©2025 Otsuka America Pharmaceutical, Inc. All rights reserved.
October 2025 23US25EXC0077

