

CAPLYTA is a prescription medication used in adults for the treatment of depressive episodes associated with bipolar I or bipolar II disorder (bipolar depression). CAPLYTA can be taken alone or with the medicines lithium or valproate for bipolar depression. It is not known if CAPLYTA is safe and effective in children.

Important Safety Information

Medicines like CAPLYTA can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). CAPLYTA is not approved for treating people with dementia-related psychosis.

CAPLYTA and antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults especially within the first few months of treatment or when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients and their families or caregivers should watch for new or worsening depression symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when CAPLYTA or an antidepressant medicine is started or when the dose is changed. Report any change in these symptoms to your healthcare provider immediately.

BIPOLAR DISORDER?

Bipolar disorder is a common mental health condition that causes extreme changes in mood and behavior.

These changes you may have experienced, known as **mood episodes**, **can cause you to experience lows (depression) and highs (mania).** Mood episodes can affect many different parts of your life, including sleep, energy, activity, judgment, behavior, and the ability to think clearly. It's important to remember that symptoms may vary by person and often overlap with other mental health conditions.



MORE THAN

11 MILLION

ADULTS ARE AFFECTED BY

BIPOLAR DISORDER IN THE US.

MEN AND WOMEN
EXPERIENCE BIPOLAR DISORDER
AT SIMILAR RATES.

THE MOST COMMON

TYPES OF BIPOLAR DISORDER

ARE BIPOLAR I AND BIPOLAR II.

SIMILAR POPULATION
SIZE FOR PEOPLE WITH BIPOLAR I
AND BIPOLAR II DISORDER.

2 3

BIPOLAR DISORDER

The lows of bipolar disorder, also known as bipolar depression or depressive episodes, can make people feel sad or hopeless. They may lose interest or pleasure in most activities, even those they once enjoyed. These depressive episodes may be present through their lives, and some episodes may even last several months. Bipolar depression refers to the depressive phase, or "lows" of bipolar disorder.

There are also highs of bipolar disorder, known as manic or hypomanic episodes, which can cause people to feel euphoric, impulsive, unusually irritable, or have an abnormal amount of increased energy. Symptoms during hypomanic episodes are milder than manic episodes.

THE LOWS

People with bipolar depression typically spend more time in the lows than in the highs of the illness.

The lows can be the **more debilitating** state for some people and may have a **greater impact than manic episodes** on everyday function.

of people report SEVERE
IMPAIRMENT due to
DEPRESSIVE EPISODES

THE HIGHS

Manic symptoms are usually reported less frequently and can often be easily overlooked or seen as something positive rather than a sign of bipolar disorder.

MORE LIKELY
for people with
bipolar disorder
TO EXPERIENCE BIPOLAR
DEPRESSION THAN MANIA

4 5

FACTS

MANY PEOPLE WITH BIPOLAR DISORDER STRUGGLE FOR YEARS BECAUSE OF MISDIAGNOSIS.

3 IN 4 PATIENTS WITH BIPOLAR DISORDER ARE MISDIAGNOSED, MOST OFTEN WITH MAJOR DEPRESSIVE DISORDER (MDD).

ANTIDEPRESSANT MEDICATIONS

MAY WORSEN BIPOLAR SYMPTOMS.

A PROPER DIAGNOSIS IS CRITICAL.

DIFFERENCE BETWEEN
BIPOLAR I OR BIPOLAR II
DEPRESSION

AND MOST BIPOLAR MEDICATIONS ARE ONLY FDA APPROVED TO TREAT BIPOLAR I.

MANAGING BIPOLAR DEPRESSION IS POSSIBLE. FINDING THE RIGHT TREATMENT PLAN MATTERS.



TO HELP IDENTIFY SOME OF THE SYMPTOMS YOU'VE BEEN EXPERIENCING.

If you are struggling with symptoms of depression, it may be worth listing all your symptoms to help you have a better conversation with your healthcare provider, so you can get the diagnosis you need.

First, it's important to know that bipolar disorder symptoms differ from person to person.

Check the boxes of any symptoms that you may have experienced.

Symptoms of Depression

Depressed mood most of the day
 Loss of interest in things you once enjoyed
 Feelings of worthlessness or guilt
 Weight loss or gain (due to changes in how much you eat)
 Trouble falling or staying asleep, or sleeping too much
 Feeling irritated easily
 Fatigue or loss of energy

Difficulty thinking, concentrating, and making decisions

Symptoms of Mania or Hypomania

Thoughts of harming yourself

- ☐ Feeling very up, high, elated
- ☐ Feeling extremely irritable or touchy
- ☐ Feeling jumpy, wired, or anxious
- Racing thoughts

Decreased need for sleep
Very talkative
Feeling able to do many things at once without getting tired
Feeling unusually important or overconfident in your abilities

In addition to the above symptoms, your healthcare provider may ask you other questions to help identify bipolar disorder.

Having 1 sign or symptom alone doesn't mean you have bipolar disorder. Be sure to share all your symptoms with your healthcare provider so you can get the proper diagnosis.

Let your doctor know if you have had these experiences which can occur with bipolar disorder.

Onset of depression occurred either before the age of 25 or after childbirth
Have tried and failed antidepressants
Family history of relatives who attempted or died by suicide or have a family member with mental illness or substance abuse
Have other conditions such as anxiety, attention-deficit/ hyperactivity disorder, misuse of drugs, eating disorders, or post-traumatic stress disorder
Have relationship difficulties or issues with employment

You can also complete the **Mood Disorder Questionnaire** on the back and discuss with your healthcare provider.

This checklist is provided as a resource by Intra-Cellular Therapies. It is not a diagnostic tool or a substitute for a full medical evaluation. Bipolar disorder is a complex illness, and an accurate, thorough diagnosis can only be made through a personal evaluation by your healthcare provider.

Please see <u>Indication and Important Safety Information</u>, including Boxed Warnings in attached brochure, or at CAPLYTA.com

QUESTIONNAIRE

Answer each of the following questions and share with your healthcare provider at your next appointment.

1. Has there ever been a period of time when you were not your usual self and:				
You felt so good or so hyper that other people thought you were not your normal self, or you were so hyper that you got into trouble?	□Y □N			
You were so irritable that you shouted at people or started fights or arguments?	□Y □N			
You felt much more self-confident than usual?	\square Y \square N			
You got much less sleep than usual and found that you didn't really miss it?	□Y □N			
You were more talkative or spoke much faster than usual?	□Y □N			
Thoughts raced through your head, or you couldn't slow your mind down?	□Y □N			
You were so easily distracted by things around you that you had trouble concentrating or staying on track?	□Y □N			
You had much more energy than usual?	\square Y \square N			
You were much more active or did many more things than usual?	□Y □N			
You were much more social or outgoing than usual; for example, you telephoned friends in the middle of the night?	□Y□N			
You were much more interested in sex than usual?	□Y□N			
You did things that were unusual for you or				

that other people might have thought were

Spending money got you or your family into

excessive, foolish, or risky?

trouble?

 \square Y \square N

 \square Y \square N

2.	If you checked Yes to more than one of the above, have several of these ever happened during the same period of time? $\square Y \square N$			
3.	How much of a problem did any of these cause			

you? (Like being una	ble to work; having family,	
money, or legal troubles; and/or getting into arguments or fights).		
□ No Problem	☐ Minor Problem	

☐ No Froblem	
■ Moderate Problem	Serious Problem

This questionnaire is provided as a resource by Intra-Cellular Therapies. It is not a diagnostic tool or a substitute for a full medical evaluation. Bipolar disorder is a complex illness, and an accurate, thorough diagnosis can only be made through a personal evaluation by your healthcare provider.



Reference: Development and Validation of a Screening Instrument for Bipolar Spectrum Disorder: The Mood Disorder Questionnaire. Robert M.A. Hirschfeld, Janet B.W. Williams, Robert L. Spitzer, Joseph R. Calabrese, Laurie Flynn, Paul E. Keck, Jr., Lydia Lewis, Susan L. McElroy, Robert M. Post, Daniel J. Rapport, James M. Russell, Gary S. Sachs, and John Zajecka. American Journal of Psychiatry.2000. 157:11, 1873-1875.

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CAPLYTA is proven to provide significant relief from depressive symptoms for bipolar disorder in adults.



Studies have also shown CAPLYTA can reduce the overall severity of bipolar depression.



Unlike some medications that only treat bipolar I, CAPLYTA treats both bipolar I and bipolar II depression and can be taken alone or with lithium or valproate.

HOW DOES CAPLYTA WORK?

CAPLYTA is a once-daily pill that's believed to work by affecting chemicals in the brain that are involved in mood, including serotonin and dopamine.

The exact way CAPLYTA works is not fully understood.

Important Safety Information

Do not take CAPLYTA if you are allergic to any of its ingredients. Get emergency medical help if you are having an allergic reaction (for example: rash, itching, hives, swelling of the tongue, lip, face, or throat).

CAPLYTA may cause serious side effects, including:

• Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.

ONCE-DAILY DOSING

CAPLYTA EFFECTIVELY TREATS BIPOLAR I AND BIPOLAR II DEPRESSION WITH A ONCE-DAILY PILL.



ONE PILL



ONCE A DAY



TAKEN WITH OR WITHOUT FOOD

MEDICATIONS FOR BIPOLAR DEPRESSION TAKE TIME TO WORK.

Even if you're not immediately seeing the results you expected, continue taking CAPLYTA as prescribed by your doctor. With no titration needed, you're on the effective dose of CAPLYTA from the start.

Keep in mind that it may take several weeks to work with your body. Talk to your doctor about all the medicines you're taking, since there are some risks for drug interactions.



Important Safety Information

CAPLYTA may cause serious side effects, including:

 Neuroleptic malignant syndrome (NMS): high fever, confusion, changes in your breathing, heart rate, and blood pressure, stiff muscles, and increased sweating; these may be symptoms of a rare but potentially fatal condition. Contact your healthcare provider or go to the emergency room if you experience signs and symptoms of NMS.



WHAT TO EXPECT WITH CAPLYTA

IN SHORT-TERM (6 WEEKS) AND LONG-TERM (6 MONTHS) CLINICAL TRIALS:



MOST PEOPLE WHO TOOK CAPLYTA DID NOT GAIN WEIGHT.

At 6 months, the average weight change for people taking CAPLYTA was **-0.02 lbs**. CAPLYTA may cause weight gain. You and your healthcare provider should monitor your weight.



MOST PEOPLE DID NOT HAVE A CHANGE IN THEIR BLOOD SUGAR OR CHOLESTEROL.

CAPLYTA may cause serious side effects, including problems with your metabolism such as increased blood sugar and fat levels (cholesterol and triglycerides) in your blood. Your healthcare provider should check your blood sugar and fat levels before you start, or soon after you start CAPLYTA, and then periodically during treatment with CAPLYTA.



MOST PEOPLE WHO TOOK CAPLYTA DID NOT EXPERIENCE MOVEMENT DISORDERS.

Movement disorders, including inner feelings of restlessness or the need to move around (akathisia) were not common when taking CAPLYTA.

CAPLYTA may cause serious side effects, including uncontrolled body movements (tardive dyskinesia, TD) in your face, tongue, or other body parts. TD may not go away, even if you stop taking CAPLYTA. It may also occur after you stop taking CAPLYTA.



The most common side effects experienced by people with bipolar depression taking CAPLYTA were sleepiness, dizziness, nausea, and dry mouth.

Important Safety Information

CAPLYTA may cause serious side effects, including:

• Problems with your metabolism including high blood sugar, diabetes, increased fat (cholesterol and triglyceride) levels in your blood and weight gain. Your healthcare provider should check your blood sugar, fat levels and weight before you start and during your treatment with CAPLYTA. Extremely high blood sugar levels can lead to coma or death. Call your healthcare provider if you have any of the following symptoms of high blood sugar: feeling very thirsty, hungry, sick to your stomach, needing to urinate more than usual, weak/tired, or confused, or your breath smells fruity.



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CAPLYTA and antidepressant medicines may increase suicidal thoughts and actions in some children, adolescents, and young adults especially within the first few months of treatment or when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients and their families or caregivers should watch for new or worsening depression symptoms, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when CAPLYTA or an antidepressant medicine is started or when the dose is changed. Report any change in these symptoms to your healthcare provider immediately.

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CAPLYTA may cause serious side effects, including:

- Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that can lead to death.
- Neuroleptic malignant syndrome (NMS): high fever, confusion, changes in your breathing, heart rate, and blood pressure, stiff muscles, and increased sweating; these may be symptoms of a rare but potentially fatal condition. Contact your healthcare provider or go to the emergency room if you experience signs and symptoms of NMS.
- Uncontrolled body movements (tardive dyskinesia, TD) in your face, tongue, or other body parts. TD may not go away, even if you stop taking CAPLYTA. It may also occur after you stop taking CAPLYTA.
- Problems with your metabolism including high blood sugar, diabetes, increased fat (cholesterol and triglyceride) levels in your blood and weight gain. Your healthcare provider should check your blood sugar, fat levels and weight before you start and during your treatment with CAPLYTA. Extremely high blood sugar levels can lead to coma or death. Call your healthcare provider if you have any of the following symptoms of high blood sugar: feeling very thirsty, hungry, sick to your stomach, needing to urinate more than usual, weak/tired, or confused, or your breath smells fruity.
- Low white blood cell count. Your healthcare provider may do blood tests during the first few months of treatment with CAPLYTA.

- Decreased blood pressure (orthostatic hypotension). You may feel lightheaded, dizzy, or faint when you rise too quickly from a sitting or lying position.
- Falls. CAPLYTA 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 broken bones or other injuries.
- Seizures (convulsions).
- Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities. Until you know how CAPLYTA affects you, do not drive, operate heavy machinery, or do other dangerous activities.
- Problems controlling your body temperature so that you feel too warm. Avoid getting overheated or dehydrated while taking CAPLYTA.
- Difficulty swallowing that can cause food or liquid to get into the lungs.

The most common side effects of CAPLYTA include sleepiness, dizziness, nausea, and dry mouth.

These are not all the possible side effects of CAPLYTA. Tell your healthcare provider if you have or have had heart problems or a stroke, high or low blood pressure, diabetes, or high blood sugar, problems with cholesterol, have or have had seizures (convulsions), kidney or liver problems, or a low white blood cell count. CAPLYTA may cause fertility problems in females and males. You should notify your healthcare provider if you become pregnant or intend to become pregnant while taking CAPLYTA. CAPLYTA may cause abnormal involuntary movements and/or withdrawal symptoms in newborn babies exposed to CAPLYTA during the third trimester. Talk to your healthcare provider if you breastfeed or are planning to breastfeed as CAPLYTA passes into breast milk. Tell your healthcare provider about all the medicines you're taking. CAPLYTA may affect the way other medicines work, and other medicines may affect how CAPLYTA works, causing possible serious side effects. Do not start or stop any medicines while taking CAPLYTA without talking to your healthcare provider. You are encouraged to report negative side effects of prescription drugs. Contact Intra-Cellular Therapies, Inc. at 1-888-611-4824 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

CAPLYTA is available in 10.5 mg, 21 mg, and 42 mg capsules.

Please see enclosed <u>Medication Guide</u>, including Boxed Warnings.

14 15

YOUR HEALTHCARE PROVIDER ABOUT CAPLYTA

Your healthcare provider's appointments are great times to let them know about how things are going with your medication and your life. They're also great times to ask questions about things that you are curious or concerned about. It helps to mention how well your symptoms are being controlled or if you are having trouble with side effects.

Here are some additional questions you may find helpful to ask your healthcare provider about CAPLYTA:

- Can CAPLYTA help with my bipolar depression symptoms?
- How quickly will CAPLYTA start working?
- What are the side effects of CAPLYTA and are they different from other bipolar depression medications?
- Do I need to take CAPLYTA with food?
- Will CAPLYTA make me gain weight?
- Can I take other medications with CAPLYTA?
- Do you think CAPLYTA would be right for me?

NEXT HEALTHCARE VISIT

It's also OK if you forget to ask something during the appointment. One tip is to keep a little notepad with you or at home to use whenever you think of anything that you want to ask. Then, you can bring it up at your next appointment or call your healthcare provider about it.

NOTES:					

Important Safety Information

CAPLYTA may cause serious side effects, including:

- Low white blood cell count. Your healthcare provider may do blood tests during the first few months of treatment with CAPLYTA.
- Decreased blood pressure (orthostatic hypotension).
- You may feel lightheaded, dizzy, or faint when you rise too quickly from a sitting or lying position.



LEARN HOW TO GET YOUR SAVINGS CARD

PAY AS LITTLE AS

FOR FIRST TWO FILLS
Up to a 30-day supply

515 FOR SUBSEQUENT FILLS OF CAPLYTA

Up to a 90-day supply

ACCESS YOUR CAPLYTA SAVINGS CARD VIA TEXT OR SCAN THE QR CODE TO DOWNLOAD IT FROM OUR WEBSITE.



to download a digital CAPLYTA Savings Card to your phone and receive useful text messages about your prescription.

- Alerts on prescription savings
- Updates on insurance coverage
- Refill reminders and the option to order refills via text

Message and data rates may apply. Message frequency varies. Text HELP for help. Text STOP to end. See <u>Terms and Conditions</u> and <u>Privacy Policy</u>.

DOWNLOAD THE SAVINGS CARD

Scan the QR code to download and print your Savings Card from our website. Then, simply bring it to your pharmacy, show it to the pharmacist, and start saving on your CAPLYTA prescriptions.



*By using the CAPLYTA Savings Card, you acknowledge that you currently meet all Eligibility Criteria and Terms & Conditions and will comply with the terms and conditions below.

PROGRAM ELIGIBILITY CRITERIA AND TERMS & CONDITIONS:

This offer is valid for eligible new or existing patients who are filling a prescription for CAPLYTA.

Patients must be 18 years of age or older, residents of the United States, excluding Puerto Rico, and have a valid prescription for CAPLYTA.

Patients must have private commercial insurance. Offer is <u>not</u> valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). This offer is not insurance, has no cash value and may not be used in combination with any other discount, coupon, rebate, free trial, savings, or similar offer.

This savings card is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your private insurance plan or other private health or pharmacy benefit programs. You must deduct the value of this savings card from any reimbursement request submitted to your private insurance plan, either directly by you or on your behalf. You are responsible for reporting use of the savings card to any private commercial insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the savings card, as may be required. You should not use the savings card if your insurer or health plan prohibits use of manufacturer savings cards.

This offer is good only at participating retail pharmacies. This card may not be redeemed for cash. Void if prohibited by law, taxed, or restricted. Eligible patients may pay as little as \$0 on the first two fills, up to the maximum lifetime benefit based on current list price of 30-day supply. On subsequent uses, eligible patients may pay as little as \$15, up to the maximum benefit of \$600. Program benefit calculated on FDA-approved dosing. A valid Prescriber ID# is required on the prescription. Intra-Cellular Therapies reserves the right to rescind, revoke, or amend this offer without notice at any time.



Data related to the redemption of this savings card may be collected, analyzed, and shared with Intra-Cellular Therapies for market research and/or other purposes related to assessing the CAPLYTA Savings Program.

By using this offer, you authorize the CAPLYTA Savings Program to share your prescription information with CoverMyMeds so that CoverMyMeds may contact your healthcare provider to request submission of information to support coverage of your CAPLYTA prescription by your health insurance plan.

This program is valid through 04/30/2025.

No other purchase is necessary.

Intra-Cellular Therapies reserves the right to rescind, revoke, or amend this offer without notice.

Patients with questions about the CAPLYTA Savings Card should call 1-800-639-4047.

Pharmacist: When you apply this offer, you are certifying that you have not submitted a claim for reimbursement under any federal, state, or other governmental programs for this prescription. This offer is valid only for patients with commercial insurance. Participation in this program must comply with all applicable laws and regulations as a pharmacy provider. By participating in this program, you are certifying that you will comply with the terms & conditions described in the Restrictions section below.

Pharmacist instructions for a patient with an Eligible Third Party: Submit the claim to the primary Third-Party Payer first, then submit the balance due to **Change Healthcare** as a Secondary Payer as a copay-only billing using a valid Other Coverage Code. Eligible patients may pay as little as \$0 on the first two uses, up to the maximum lifetime benefit based on current list price of 30-day supply. On subsequent uses, eligible patients may pay as little as \$15, up to the maximum benefit of \$600. Reimbursement will be received from **Change Healthcare**.

For any questions regarding **Change Healthcare** online processing, please call the Help Desk at 1-800-433-4893.

Restrictions: This offer is valid in the United States, excluding Puerto Rico. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). This offer is valid only for patients with commercial insurance. Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. It is illegal to (or offer to) sell, purchase, or trade this offer. Program expires 04/30/2025. This offer is not transferable and is limited to one offer per person. Not valid if reproduced. Void where prohibited by law. Program managed by ConnectiveRx

Intra-Cellular Therapies reserves the right to rescind, revoke, or amend this offer without notice at any time.

on behalf of Intra-Cellular Therapies.



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 bones or other injuries.
- Seizures (convulsions).
- Sleepiness, drowsiness, feeling tired, difficulty thinking and doing normal activities. Until you know how CAPLYTA affects you, do not drive, operate heavy machinery, or do other dangerous activities.



TO HELP LYTE YOUR WAY

GET GOING WITH THESE HEALTH TIPS

CAPLYTA may help with managing your bipolar depression, but there are other things that you can do each day to rise above the lows of depressive episodes.

Look forward to what's ahead. Make a list of things you'd like to do.

Talk to friends and family. They'd love to hear from you and may enjoy doing some of the things you want to do, too.

Keep a sleep schedule. Sleeping at the same time each night may help with maintaining a daily routine.

Stay active. From taking a walk to joining a gym, exercise may help you feel better physically and emotionally.

Eat well. A healthy diet is not only good for your physical health, but may also support your mental well-being.

Keep track of your moods. Each day is different, so it's important to note how you feel and what made you feel that way.

Reach out when you need to. Your healthcare provider can help with creating a treatment plan that works best for you.

SUPPORT

There are many organizations that offer support and education and help form important connections for persons with bipolar disorder.

DBSA (Depression and Bipolar Support Alliance)

Website: dbsalliance.org

DBSA provides hope, help, support, and education to improve the lives of people who have mood disorders (depression and bipolar disorder).

NAMI (National Alliance on Mental Illness)

Website: nami.org

NAMI is an organization dedicated to building better lives for the millions of Americans with mental illness.

MHA (Mental Health America)

Website: mentalhealthamerica.net

Mental Health America is a community-based nonprofit dedicated to addressing the needs of those living with mental illness.

AFSP (American Foundation for Suicide Prevention)

Website: afsp.org

AFSP raises awareness, funds scientific research, and provides resources and aid to those affected by suicide.

NIMH (National Institute of Mental Health)

Website: nimh.nih.gov

The National Institute of Mental Health is the lead federal agency for research on mental disorders.

Important Safety Information

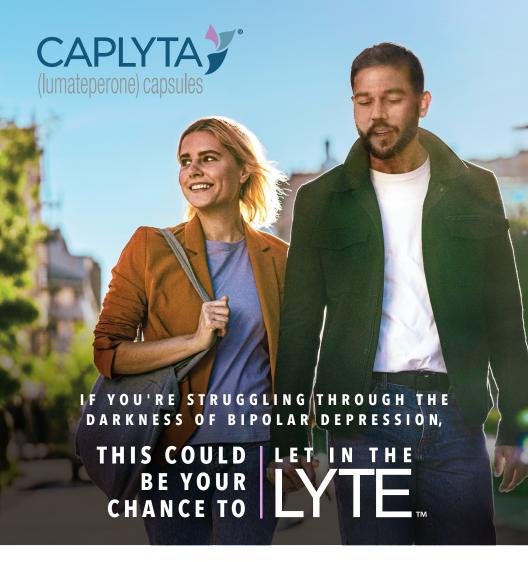
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- Problems controlling your body temperature so that you feel too warm. Avoid getting overheated or dehydrated while taking CAPLYTA.
- Difficulty swallowing that can cause food or liquid to get into the lungs.

CAPLYTA (lumateperone) capsules

NOTES	





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Please see additional Important Safety Information, including Boxed Warnings, on pages 14–15.



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