

Helpful resources for people  
living with bipolar depression



# Latuda<sup>®</sup>

(lurasidone HCl)

The lows of bipolar depression can disrupt your life.

**LATUDA** could make  
*a real difference* in your symptoms.

LATUDA is a prescription medicine approved to treat bipolar depression in adults and in children/teens (10 to 17 years) alone, and in adults taking lithium or valproate.

#### IMPORTANT SAFETY INFORMATION FOR LATUDA

**INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; and SUICIDAL THOUGHTS AND BEHAVIORS**

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

Antidepressant medicines may increase suicidal thoughts or behaviors in some children, teenagers, and young adults within the first few months of treatment and when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients on antidepressants 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 an antidepressant medicine is started or when the dose is changed. Report any change in these symptoms immediately to the doctor.

**Please see Important Safety Information, including Boxed Warning, on pages 24–27 and Medication Guide on pages 29–30.**

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Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24-27 and Medication Guide on pages 29-30.



# Understanding bipolar depression

Bipolar depression is part of a larger condition called bipolar disorder. Symptoms, such as mood changes, may occur during childhood, adolescence, or adulthood and can vary in length and severity.

Bipolar depression refers to the depressive phase, or “lows,” of bipolar I disorder. There is also a manic, or “high,” phase of bipolar I disorder where you might feel energized or really agitated.

To be diagnosed with bipolar depression, you must have had at least one manic period in your life, along with repeated lows. You might hear these highs and lows referred to as episodes. Latuda® (lurasidone HCl) is a treatment specifically for the low, or depressive, episodes.

## The impact of bipolar depression

Depressive symptoms such as sadness, emptiness, and hopelessness are at the core of bipolar depression. Living with these symptoms day in and day out could be holding you back.

People with bipolar depression can struggle for years with low moods that keep coming back.

Most will go through more and longer low periods than high ones—with **the lows of bipolar disorder being 3x more common than the highs.**

**The important thing to remember is that bipolar depression can be managed.** The way it's treated may be different from other types of depression, so it's important to understand your diagnosis and find a treatment plan for bipolar depression. The right treatment plan could make a real difference in your symptoms.

If you're struggling to manage the lows of bipolar depression, ask your doctor about LATUDA. LATUDA is a once-a-day prescription medicine approved by the FDA to treat bipolar depression in adults and in children/teens (10 to 17 years) alone, and in adults taking lithium or valproate.

## Know the signs and symptoms of bipolar depression

Bipolar depression can present in different ways. You may experience:

- Loss of energy and feeling depressed or sad most of the time
- Difficulty sleeping—either sleeping too much or not at all
- Changes in appetite—eating too much or too little
- Difficulty concentrating, remembering, or making decisions
- Thoughts of death or suicide

Having one sign or symptom alone doesn't mean you have bipolar depression. Talk to your doctor about your signs and symptoms.

## Did you know?

Children and teens can develop bipolar depression just like adults. However, their symptoms may differ slightly. In addition to the symptoms above, children and teens may appear more irritable than sad.

**IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)**  
LATUDA 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) is a serious condition that can lead to death.** Call your health care provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS: high fever, increased sweating, stiff muscles, confusion, or changes in your breathing, heart rate, and blood pressure

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# Bipolar depression may be *difficult to diagnose*

Diagnosing bipolar depression can be tough. The reason?

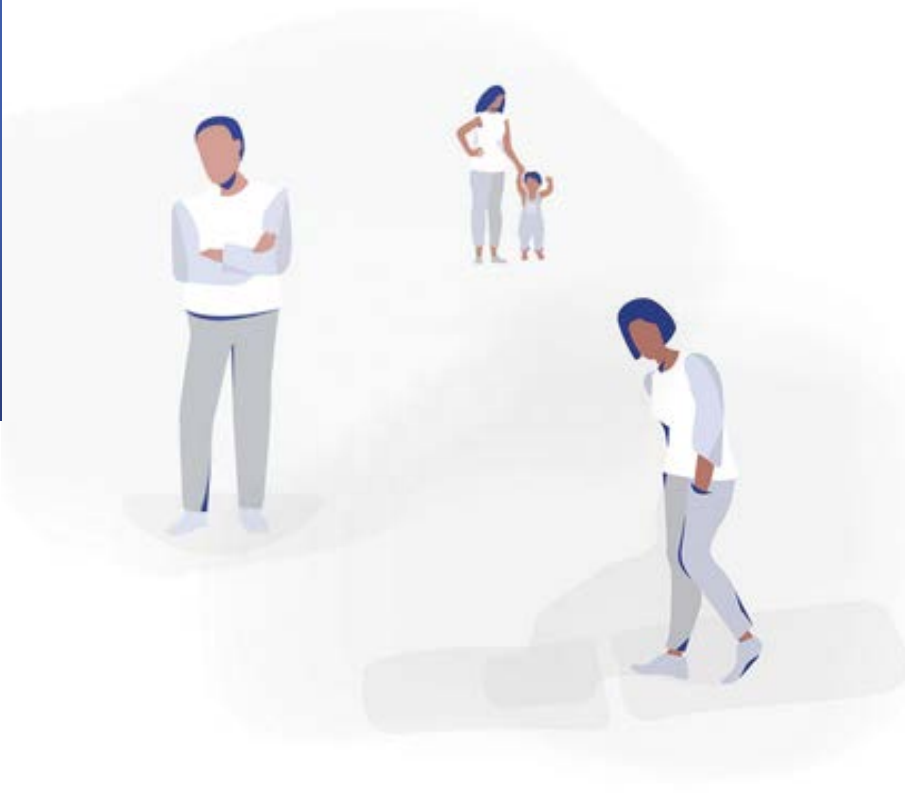
You may see your doctor because you are struggling with the lows of bipolar depression. When you are feeling low, it can be easy to forget any time when you felt really “high.” You may even think that feeling energized or revved up is just your depression getting better. But it may be more. It may be a sign of a manic, or high, episode, which is what distinguishes bipolar depression from other types of depression.

That is why it is important to share ALL of your mood symptoms with your doctor. Your description of your symptoms can help your doctor decide if you have bipolar depression. Latuda® (lurasidone HCl) specifically treats the lows, or depressive episodes, of bipolar depression.

Together, you can develop the right treatment plan with your doctor.

## *Keep in mind...*

- In children and teens, bipolar disorder can be difficult to tell apart from other disorders, including attention-deficit/hyperactivity disorder (ADHD). However, it is common for people to have both bipolar disorder and another disorder such as ADHD
- Family history is one of the strongest risk factors for bipolar disorder. Tell your doctor if someone else in your family has bipolar disorder or another mental illness



**If you have thoughts about suicide, call your doctor right away or go to the emergency room.**

**The National Suicide Prevention Lifeline is available 24 hours a day by calling 988.**

## **IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)** **LATUDA may cause serious side effects, including:**

- **Problems with your metabolism such as:**
  - **High blood sugar (hyperglycemia) and diabetes:** Increases in blood sugar can happen in some people who take LATUDA. 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 health care provider should check your blood sugar before you start and during treatment with LATUDA

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24–27 and Medication Guide on pages 29–30.

# Tips for living well with bipolar depression.

Living well with bipolar depression is an ongoing process. Your doctor is a good resource to help keep you on track. There are also things you can try to do on a daily basis to help. Here are a few helpful tips to start with:



Check in with family and friends—whether in person, over the phone, or video chat.



Especially during difficult times, find something to be grateful for every day.



Remember that healthy eating is good for you physically, mentally, and emotionally.



Being active, outdoors or in, can help you feel good about yourself.



Go to bed at the same time every night. This helps us maintain a regular sleep schedule.



Focus on what you can do. Then plan to make it happen. It helps show what is possible when you feel in control.



Make a list of what you'd like to accomplish in your daily routine, even if your routine changes.



Remember, you may be able to connect with your doctor in different ways (phone, email, or video chat) if you feel that you can't manage on your own.

## Managing bipolar depression is a *team effort*

It can be difficult to ask for help. However, building a support system is an important part of managing bipolar depression.

A strong support system is based on open and honest communication with those who care about you. Your support team includes your doctors, as well as anyone involved in helping your recovery, such as family, friends, coworkers, teachers, and schoolmates.

### *Working with your treatment team*

Your treatment team may be made up of trained experts. But you're the expert when it comes to you and your treatment goals.

If you feel like your symptoms or feelings need attention, talk to your doctor or care team. If you can't see them in person, phone or video chat options may be available.

#### **IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)**

- **Call your health care provider if you have any of these symptoms of high blood sugar (hyperglycemia) while taking LATUDA:** 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

#### **LATUDA may cause serious side effects, including:**

- **Problems with your metabolism such as:**
  - Increased fat levels (cholesterol and triglycerides) in your blood

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24–27 and Medication Guide on pages 29–30.

## Getting to know your treatment team

- **Psychiatrist:** A physician who receives additional training to specialize in the prevention, diagnosis, and treatment of mental illness; can prescribe medication.
- **Nurse practitioner (NP):** A registered nurse with advanced training in a medical specialty, such as mental health; can prescribe medication in some states.
- **Physician assistant (PA):** A medical professional who can diagnose, treat, and prescribe medication under the supervision of a licensed physician.
- **Psychologist:** A healthcare provider who specializes in diagnosing and treating diseases of the brain, emotional disturbance, and behavior issues; can treat people living with bipolar depression with talk therapy; cannot prescribe medication in most states.
- **Social worker or counselor/therapist:** A trained professional who specializes in thought- and action-related coping skills; can treat people living with bipolar depression with talk therapy; cannot prescribe medication.
- **General practitioner (GP):** A physician who does not specialize in a specific field of medicine; sometimes referred to as a primary care physician (PCP); can prescribe medicine.
- **Pediatrician:** A physician who specializes in the medical care of infants, children, and adolescents; can prescribe medicine.

In addition to your treatment team, your prescribed medication and treatment plan is the other key component that can help you manage your bipolar depression symptoms.



## What is LATUDA?

LATUDA is a prescription medicine approved to treat bipolar depression in adults and in children/teens (10 to 17 years) alone, and in adults taking lithium or valproate.



### Significantly reduced bipolar depression symptoms

In 6-week clinical studies compared to placebo. Results may vary.



### No substantial impact on weight in adults

95% of adults taking LATUDA in bipolar depression studies saw no clinically meaningful impact on weight (defined as a  $\geq 7\%$  change at 6 weeks). Weight gain may occur. You and your doctor should monitor your weight regularly.

## What to expect with LATUDA

Everyone responds to medication differently. LATUDA works gradually, so it may take some time to see results.

It's also important to know the possible side effects of LATUDA. This way you and your doctor can create the right treatment plan for you.

### IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)

LATUDA may cause serious side effects, including:

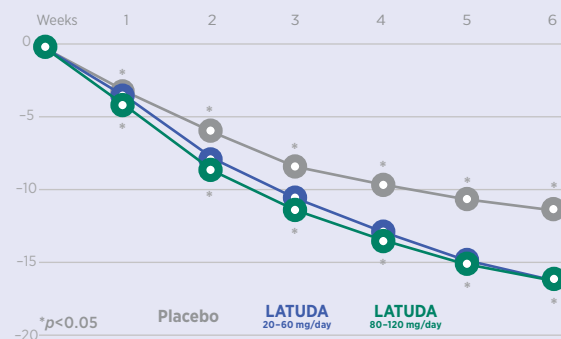
- **Problems with your metabolism such as:**
  - **Weight gain.** You and your health care provider should check your weight regularly during treatment with LATUDA

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24–27 and Medication Guide on pages 29–30.

# Proven symptom reduction with LATUDA

In studies with adults, LATUDA was proven to reduce bipolar depression symptoms at 6 weeks

Reduction in depressive symptoms vs placebo



44%  
GREATER  
REDUCTION  
IN SYMPTOMS  
VS PLACEBO  
WHEN TAKEN  
ALONE

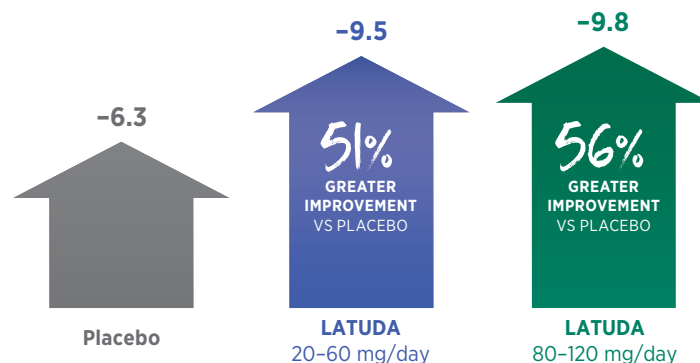
Adults who are already taking a mood stabilizer (lithium or valproate) can add LATUDA to help reduce their depressive symptoms

In clinical studies, people who added LATUDA to a mood stabilizer\* saw their depressive symptoms reduced by 27% vs placebo.

\*Studied in adults taking lithium or valproate.

In studies, adults who took LATUDA reported improved scores in their ability to function

Change in total functioning score vs placebo at 6 weeks\*



\*Based on total scores from the Sheehan Disability Scale, which measures functional impairment. A reduction in this score indicates an improvement.

Adults who added LATUDA to the mood stabilizer they were already taking (lithium or valproate) also reported improvements in their total functioning scores

In clinical studies, people who added LATUDA to a mood stabilizer reported a 36% greater improvement in total functioning score vs placebo at 6 weeks.

Mean change in score from baseline was -9.5 for the LATUDA + lithium or valproate group and -7.0 for the placebo + lithium or valproate group.

**The main objective (primary endpoint) measured at the end of LATUDA clinical studies was the reduction in bipolar depressive symptoms. Another objective in these clinical studies was to measure the impact of LATUDA on functioning as a secondary endpoint. These results should be interpreted with caution as they are observational and descriptive in nature.**

**IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)**  
LATUDA may cause serious side effects, including:

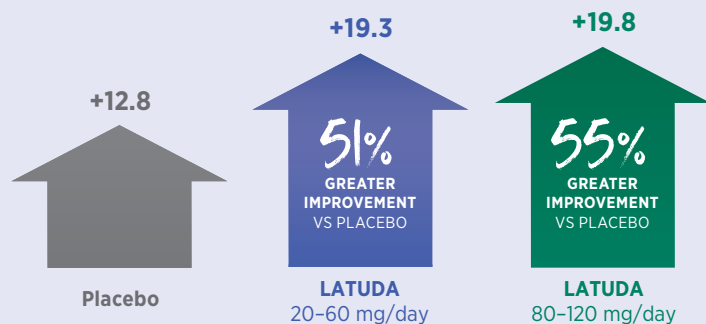
- **Low white blood cell count.** Your health care provider may do blood tests during the first few months of treatment with LATUDA
- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24-27 and Medication Guide on pages 29-30.



In studies, adults who took LATUDA reported improved scores in their quality of life

Change in total quality of life score vs placebo at 6 weeks\*



\*Based on total scores from the Quality of Life, Enjoyment, and Satisfaction Questionnaire, which measures quality of life.

**Adults who added LATUDA to the mood stabilizer they were already taking (lithium or valproate) also reported improvements in their total quality of life scores**

In clinical studies, people who added LATUDA to a mood stabilizer reported a 40% greater improvement in total quality of life score vs placebo at 6 weeks.

Mean change in score from baseline was +22.2 for the LATUDA + lithium or valproate group and +15.9 for the placebo + lithium or valproate group.

**The main objective (primary endpoint) measured at the end of LATUDA clinical studies was the reduction in bipolar depressive symptoms. Another objective in these clinical studies was to measure the impact of LATUDA on quality of life as a secondary endpoint. These results should be interpreted with caution as they are observational and descriptive in nature.**

## FAQs about LATUDA

### What are the most common side effects of LATUDA?

The most common side effects of LATUDA are:

- Adults with bipolar depression: restlessness or feeling like you need to move around (akathisia); difficulty moving or slow movements; and sleepiness or drowsiness
- Children (10 to 17 years) with bipolar depression: nausea; weight gain; and problems sleeping (insomnia)

### Who should not take LATUDA?

The following people should not take LATUDA:

- People who are allergic to lurasidone hydrochloride or any of the ingredients in LATUDA. See the end of the Medication Guide for a complete list of ingredients in LATUDA
- People who are taking certain other medicines called CYP3A4 inhibitors or inducers including ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, rifampin, avasimibe, St. John's wort, phenytoin, or carbamazepine. Ask your doctor if you are not sure if you are taking any of these medicines

### How long should LATUDA be taken?

Only your doctor should advise which medications you should take, and for how long.

### IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl) LATUDA may cause serious side effects, including:

- **Falls.** LATUDA 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
- **Seizures (convulsions)**

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24-27 and Medication Guide on pages 29-30.



# Discuss bipolar depression with your doctor

Fill out the questions below. Talk to your doctor about how you're doing. Together, you can find the right treatment plan to help with your symptoms.

*Let's start:*



How are you feeling overall? Think about the last 30 days. Have you felt stable most days, or depressed and/or sad?

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What challenges are keeping you from reaching your treatment goals?

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How have the lows of bipolar depression affected your energy level, moods, or sleeping habits?

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What symptoms are you having?

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Have more questions for your doctor? Jot them down here:

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Visit [LATUDA.com](http://LATUDA.com) and download the Daily Mood Monitor. It can help you and your doctor get a clearer picture of how bipolar depression is impacting you during the month.

Ask if LATUDA could help make the difference you've been looking for in your bipolar depression symptoms.

**IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)**  
LATUDA may cause serious side effects, including:

- **Mania or hypomania** (manic episodes) in people with a history of bipolar disorder. Symptoms may include: greatly increased energy, severe problems sleeping, racing thoughts, reckless behavior, unusually grand ideas, excessive happiness or irritability, or talking more or faster than usual

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# Supporting you every step of the way

## Sunovion answers for all of your questions

Sunovion Answers can help you understand what LATUDA is, what your insurance covers, what your copay may be for your LATUDA prescription, what copay savings programs are available, and much more.

*Our award-winning* support specialists  
are here to assist with:

- Additional detailed information about LATUDA
- Answering questions about insurance coverage and benefits
- Delivering support and resources when you need them

Learn more at [sunovionanswers.com](https://www.sunovionanswers.com) or call **1-855-5LATUDA** (1-855-552-8832) anytime between 8 AM and 8 PM (ET) Monday through Friday.

## Looking for help staying on track throughout your treatment journey?

Stay supported with resources designed around you, including:

- Tools to track your progress
- Email support
- Help with cost and coverage options

## Keep your doctor in the know

It's important to keep your doctor updated on how you've been feeling since starting LATUDA.

That way they can make adjustments to your treatment plan, as needed.

**IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)**  
LATUDA may cause serious side effects, including:

- **Difficulty swallowing**

**Do not** drive, operate heavy machinery, or do other dangerous activities until you know how LATUDA affects you. LATUDA may make you drowsy.

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24–27 and Medication Guide on pages 29–30.

# Copay savings start with an offer from LATUDA<sup>†</sup>

## Pay as little as \$0 with 90-day prescription fills<sup>‡</sup>

Eligible patients may pay as little as \$0 for all 90-day prescription fills OR your first 30-day prescription fill.<sup>‡</sup>  
\$10 for 30-day refills.<sup>‡</sup>



Show the card at your pharmacy each time you fill or refill your prescription, or use the card for mail-order prescriptions, and you could be on your way to savings.



**NOTE: Due to State law, residents of MA are not eligible for this copay program.**

<sup>†</sup>Exclusions apply.

<sup>‡</sup>Due to State law, residents of MA are not eligible for this copay program. Must meet all other eligibility requirements. For commercially insured patients, this Copay Savings Card covers out-of-pocket expenses to a maximum benefit of \$400 for a 30-day supply or \$1200 for a 90-day supply. The Card allows up to twelve 30-day supply uses or four 90-day supply uses in a calendar year with a valid prescription. Please see full terms and conditions at [latuda.com/bpd/latuda-savings-and-support.html#terms](https://latuda.com/bpd/latuda-savings-and-support.html#terms).

You may be able to get your LATUDA prescription filled via the mail. A mail-order prescription can save you trips to the pharmacy by delivering your medicine to your door.

When using the Copay Savings Card with the mail-order pharmacy option, follow these 2 simple steps:

-  1 After receiving your prescription in the mail, visit [patientrebateonline.com](https://patientrebateonline.com) to enter your Copay Savings Card ID. If you don't have it, you can search for it through the "information requested" feature.
-  2 Fill out your information and upload the required documents. Click submit.  
  
Once your request is processed, you should receive a confirmation email and can expect to receive your LATUDA medication in 7 to 15 business days.

## Did you know?

A 90-day prescription is one way to get the medication your doctor prescribed. It can mean fewer trips to the pharmacy and may reduce out-of-pocket costs depending on your plan.

### IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)

**Avoid** eating grapefruit or drinking grapefruit juice while you take LATUDA since these can affect the amount of LATUDA in the blood.

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24–27 and Medication Guide on pages 29–30.

# What to remember when taking Latuda® (lurasidone HCl)

Talk to your doctor about how to take LATUDA. Below are a few things you may want to discuss.



**Stick with it.** Be patient. For some people, LATUDA may work gradually.



**Keep cool, stay hydrated.** Your temperature may fluctuate when taking LATUDA.



**Pass on the alcohol.** It may worsen any side effects.



**Skip the grapefruit and grapefruit juice.** They can affect the amount of LATUDA in your blood.



**Eat at least 350 calories.** Food will help your body absorb LATUDA more efficiently.



**Watch out for drowsiness.** Until you get used to LATUDA, be careful when operating machinery.



**It's ok to ask for help.** Tell your doctor if your symptoms get worse.



**Take LATUDA once-a-day.** LATUDA should always be taken exactly as your doctor prescribes.

LATUDA.com



1-855-5LATUDA  
(1-855-552-8832)

## IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)

**Do not** take LATUDA if you are allergic to any of the ingredients in LATUDA or take certain medications called CYP3A4 inhibitors or inducers. Ask your health care provider if you are not sure if you are taking any of these medications.

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24–27 and Medication Guide on pages 29–30.

## IMPORTANT SAFETY INFORMATION AND INDICATIONS FOR Latuda® (lurasidone HCl)

### INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; and SUICIDAL THOUGHTS AND BEHAVIORS

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

Antidepressant medicines may increase suicidal thoughts or behaviors in some children, teenagers, and young adults within the first few months of treatment and when the dose is changed.

Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients on antidepressants 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 an antidepressant medicine is started or when the dose is changed. Report any change in these symptoms immediately to the doctor.

LATUDA 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) is a serious condition that can lead to death.** Call your health care provider or go to the nearest hospital emergency room right away if you have some or all of the following signs and symptoms of NMS: high fever, increased sweating, stiff muscles, confusion, or changes in your breathing, heart rate, and blood pressure
- **Uncontrolled body movements (tardive dyskinesia).** LATUDA 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 taking LATUDA. Tardive dyskinesia may also start after you stop taking LATUDA
- **Problems with your metabolism such as:**
  - **High blood sugar (hyperglycemia) and diabetes:** Increases in blood sugar can happen in some people who take LATUDA. 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 health care provider should check your blood sugar before you start and during treatment with LATUDA
    - **Call your health care provider if you have any of these symptoms of high blood sugar (hyperglycemia) while taking LATUDA:** 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 health care provider should check your weight regularly during treatment with LATUDA
- **Increased prolactin levels in your blood (hyperprolactinemia).** Your health care provider may do blood tests to check your prolactin levels during treatment with LATUDA. Tell your health care provider if you have any of the following signs and symptoms of hyperprolactinemia:
  - **Females:** absence of your menstrual cycle or secretion of breast milk when you are not breastfeeding
  - **Males:** problems getting or maintaining an erection (erectile dysfunction) or enlargement of breasts (gynecomastia)
- **Low white blood cell count.** Your health care provider may do blood tests during the first few months of treatment with LATUDA
- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position
- **Falls.** LATUDA 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
- **Seizures (convulsions)**
- **Problems controlling your body temperature so that you feel too warm.** Do not become too hot or dehydrated during treatment with LATUDA. 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
- **Mania or hypomania** (manic episodes) in people with a history of bipolar disorder. Symptoms may include: greatly increased energy, severe problems sleeping, racing thoughts, reckless behavior, unusually grand ideas, excessive happiness or irritability, or talking more or faster than usual
- **Difficulty swallowing**

**Do not** drive, operate heavy machinery, or do other dangerous activities until you know how LATUDA affects you. LATUDA may make you drowsy.

**Avoid** eating grapefruit or drinking grapefruit juice while you take LATUDA since these can affect the amount of LATUDA in the blood.

**Do not** take LATUDA if you are allergic to any of the ingredients in LATUDA or take certain medications called CYP3A4 inhibitors or inducers. Ask your health care provider if you are not sure if you are taking any of these medications.

Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24–27 and Medication Guide on pages 29–30.



**Tell your health care provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. LATUDA and other medicines may affect each other, causing possible serious side effects. LATUDA may affect the way other medicines work, and other medicines may affect how LATUDA works. Your health care provider can tell you if it is safe to take LATUDA with your other medicines. Do not start or stop any other medicines during treatment with LATUDA without talking to your health care provider first.

**Before taking LATUDA, tell your health care provider about all of your medical conditions, including if you:**

- have or have had heart problems or stroke
- have or have had low or high blood pressure
- have or have had diabetes or high blood sugar, or have a family history of diabetes or high blood sugar
- have or have had high levels of total cholesterol or triglycerides
- have or have had high prolactin levels
- have or have had low white blood cell count
- have or have had seizures
- have or have had kidney or liver problems
- are pregnant or plan to become pregnant. It is not known if LATUDA will harm your unborn baby. Talk to your health care provider about the risk to your unborn baby if you take LATUDA during pregnancy
  - Tell your health care provider if you become pregnant or think you are pregnant during treatment with LATUDA
  - If you become pregnant during treatment with LATUDA, talk to your health care provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or going to <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/>
- are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into your breast milk. Talk to your health care provider about the best way to feed your baby during treatment with LATUDA

**The most common side effects of LATUDA include:**

- Adults with schizophrenia: sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, or muscle stiffness; and nausea
- Adolescents (13 to 17 years) with schizophrenia: sleepiness or drowsiness; nausea; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor; runny nose/nasal inflammation; and vomiting

- Adults with bipolar depression: restlessness or feeling like you need to move around (akathisia); difficulty moving or slow movements; and sleepiness or drowsiness
- Children (10 to 17 years) with bipolar depression: nausea; weight gain; and problems sleeping (insomnia)

These are not all the possible side effects of LATUDA. For more information, ask your health care provider or pharmacist.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

## INDICATIONS

LATUDA is a prescription medicine used:

- To treat adults and adolescents (13 to 17 years) with schizophrenia
- Alone to treat adults, children and teens (10 to 17 years) with depressive episodes that happen with bipolar I disorder (bipolar depression)
- With the medicine lithium or valproate to treat adults with depressive episodes that happen with bipolar I disorder (bipolar depression)

**Please see enclosed Medication Guide and full Prescribing Information at LATUDA.com.**


Please see additional **Important Safety Information**, including **Boxed Warning**, on pages 24–27 and Medication Guide on pages 29–30.



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LATUDA could  
*make the difference*  
you've been looking for in your  
bipolar depression symptoms



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# MEDICATION GUIDE

## LATUDA (luh-TOO-duh) (lurasidone hydrochloride) tablets

10092-03-MKT3

### What is the most important information I should know about LATUDA? LATUDA may cause serious side effects, including:

- **Increased risk of death in elderly people with dementia-related psychosis.** Medicines like LATUDA can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). LATUDA is not approved for the treatment of people with dementia-related psychosis.
- **Increased risk of suicidal thoughts or actions in children and young adults.** Antidepressant medicines may increase suicidal thoughts or actions in some children and young adults within the first few months of treatment and when the dose is changed.

- **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) depression, bipolar illness (also called manic-depressive illness), or a history of suicidal thoughts or actions.

### How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

- Pay close attention to any changes, especially sudden changes in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call a healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with the healthcare provider as scheduled. Call a healthcare provider between visits as needed, especially if you have concerns about symptoms.

### Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

### What is LATUDA?

LATUDA is a prescription medicine used:

- To treat people 13 years of age or older with schizophrenia.
- Alone to treat people 10 years of age and older with depressive episodes that happen with Bipolar I Disorder (bipolar depression).
- With the medicine lithium or valproate to treat adults with depressive episodes that happen with Bipolar I Disorder (bipolar depression).

It is not known if LATUDA is safe and effective in children:

- less than 13 years of age with schizophrenia.
- less than 10 years of age with bipolar depression.
- for the treatment of irritability associated with autistic disorder.

### Do not take LATUDA if you are:

- allergic to lurasidone hydrochloride or any of the ingredients in LATUDA. See the end of this Medication Guide for a complete list of ingredients in LATUDA.
- taking certain other medicines called CYP3A4 inhibitors or inducers including ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, rifampin, avasimibe, St. John's wort, phenytoin, or carbamazepine. Ask your healthcare provider if you are not sure if you are taking any of these medicines.

### Before taking LATUDA, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had heart problems or stroke
- have or have had low or high blood pressure
- have or have had diabetes or high blood sugar, or have a family history of diabetes or high blood sugar.
- have or have had high levels of total cholesterol or triglycerides
- have or have had high prolactin levels
- have or have had low white blood cell count
- have or have had seizures
- have or have had kidney or liver problems
- are pregnant or plan to become pregnant. It is not known if LATUDA will harm your unborn baby. Talk to your healthcare provider about the risk to your unborn baby if you take LATUDA during pregnancy.
  - Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with LATUDA.
  - If you become pregnant during treatment with LATUDA, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to <http://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/>.
- are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with LATUDA.

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

LATUDA and other medicines may affect each other causing possible serious side effects. LATUDA may affect the way other medicines work, and other medicines may affect how LATUDA works.

Your healthcare provider can tell you if it is safe to take LATUDA with your other medicines. Do not start or stop any other medicines during treatment with LATUDA without talking to your healthcare provider first.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

### How should I take LATUDA?

- Take LATUDA exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking LATUDA without first talking to your healthcare provider.
- Take LATUDA by mouth, with food (at least 350 calories).
- If you take too much LATUDA, call your healthcare provider or poison control center or go to the nearest hospital emergency room right away.

### What should I avoid while taking LATUDA?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how LATUDA affects you. LATUDA may make you drowsy.
- Avoid eating grapefruit or drinking grapefruit juice during treatment with LATUDA. Grapefruit and grapefruit juice may affect the amount of LATUDA in your blood.
- Do not become too hot or dehydrated during treatment with LATUDA.
  - 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.

### What are the possible side effects of LATUDA?

#### LATUDA may cause serious side effects, including:

- See “What is the most important information I should know about LATUDA?”
- **Stroke (cerebrovascular problems) in elderly people with dementia-related psychosis that 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 hospital emergency room right away if you have some or all of the following signs and symptoms of NMS:
  - high fever
  - stiff muscles
  - confusion
  - increased sweating
  - changes in your breathing, heart rate, and blood pressure
- **Uncontrolled body movements (tardive dyskinesia).** LATUDA 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 taking LATUDA. Tardive dyskinesia may also start after you stop taking LATUDA.
- **Problems with your metabolism such as:**
  - **high blood sugar (hyperglycemia) and diabetes.** Increases in blood sugar can happen in some people who take LATUDA. 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 and during treatment with LATUDA.  
**Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with LATUDA:**
    - 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 with LATUDA.
- **Increased prolactin levels in your blood (hyperprolactinemia).** Your healthcare provider may do blood tests to check your prolactin levels during treatment with LATUDA. Tell your healthcare provider if you have any of the following signs and symptoms of hyperprolactinemia:  
**Females:**
  - absence of your menstrual cycle
  - secretion of breast milk when you are not breastfeeding**Males:**
  - problems getting or maintaining an erection (erectile dysfunction)
  - enlargement of breasts (gynecomastia)
- **Low white blood cell count.** Your healthcare provider may do blood tests during the first few months of treatment with LATUDA.
- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
- **Falls.** LATUDA 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.
- **Seizures (convulsions)**
- **Problems controlling your body temperature so that you feel too warm.** See “What should I avoid while taking LATUDA?”

- **Mania or hypomania** (manic episodes) in people with a history of bipolar disorder. Symptoms may include:
  - greatly increased energy
  - severe problems sleeping
  - racing thoughts
  - reckless behavior
  - unusually grand ideas
  - excessive happiness or irritability
  - talking more or faster than usual

#### • **Difficulty swallowing**

#### The most common side effects of LATUDA include:

- **Adults with schizophrenia:**
  - sleepiness or drowsiness
  - restlessness and feeling like you need to move around (akathisia)
  - difficulty moving, slow movements, muscle stiffness, or tremor
  - nausea
- **Children 13 to 17 years of age with schizophrenia:**
  - sleepiness or drowsiness
  - nausea
  - restlessness and feeling like you need to move around (akathisia)
  - difficulty moving, slow movements, muscle stiffness, or tremor
  - runny nose
  - vomiting
- **Adults with bipolar depression:**
  - restlessness and feeling like you need to move around (akathisia)
  - difficulty moving, slow movements, muscle stiffness, or tremor
  - sleepiness or drowsiness
- **Children 10 to 17 years of age with bipolar depression:**
  - nausea
  - weight gain
  - problems sleeping (insomnia)

These are not all of the possible side effects of LATUDA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### How should I store LATUDA?

- Store LATUDA tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep LATUDA and all medicines out of the reach of children.

#### General information about the safe and effective use of LATUDA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LATUDA for a condition for which it was not prescribed. Do not give LATUDA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about LATUDA that is written for health professionals.

#### What are the ingredients in LATUDA?

**Active ingredient:** lurasidone hydrochloride

**Inactive ingredients:** mannitol, pregelatinized starch, croscarmellose sodium, hypromellose, magnesium stearate, Opadry® and carnauba wax. Additionally, the 80 mg tablet contains yellow ferric oxide and FD&C Blue No. 2 Aluminum Lake



Manufactured for: Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA  
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For more information, go to [www.LATUDA.com](http://www.LATUDA.com) or call 1-888-394-7377.

This Medication Guide has been approved by the U.S. Food and Drug Administration.  
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