Be there for life's little moments. Consider LATUDA for bipolar depression.

Bipolar depression medicine for adults and for children and teens (10 to 17 years)

Please see Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.

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.
Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).

Please see Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.
Ask your doctor about Latuda® (lurasidone HCl) for bipolar depression

If you or a loved one struggles with bipolar depression, there are treatment options
LATUDA is a once-a-day prescription medicine for bipolar depression in adults and in children and teens (10 to 17 years).
Bipolar disorder may be more common than some people realize. It may affect as many as 60 million people worldwide. Symptoms may occur gradually or suddenly during childhood, adolescence, or adulthood.
Bipolar depression can leave you feeling sad and empty. It can drain your energy and enthusiasm. And make it a struggle to be there for the people you love.
With the right treatment and support, bipolar depression may be manageable. The way it’s treated may be different from how other types of depression are managed. LATUDA is an FDA-approved treatment for bipolar depression.

Bipolar depression is different
There are many types of depression. In fact, depressive symptoms such as sadness, emptiness, and hopelessness are the same across most forms of depression.
Bipolar depression refers to the depressive phase, or “lows,” of bipolar I disorder. To be diagnosed with bipolar depression, a person must have had at least one manic, or “high,” period in his or her life, along with recurrent lows. These highs and lows are called episodes.
People with bipolar disorder typically spend more time in the lows than in the highs of their illness. They also tend to seek help when they’re depressed. And a high episode can be easily overlooked or seen as something positive, rather than as a possible sign of bipolar disorder. That’s why it’s important to share ALL symptoms with your health care provider, so together you can develop a treatment plan to help make living with bipolar depression more manageable.

IMPORTANT SAFETY INFORMATION 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.

Please see additional Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.

Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).
Symptoms related to bipolar disorder

Knowing the symptoms of bipolar disorder may help you and your health care provider work toward the right diagnosis and treatment. Take a look at the following signs. If they sound familiar, complete the Mood Disorder Questionnaire and discuss with your health care provider.

In addition to depressed or sad moods, symptoms of bipolar depression may include:

- No interest in activities that were once enjoyable
- Loss of energy
- 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

Children and teens often can develop depression just like adults and may show many of the symptoms above. Sometimes their mood may appear more irritable than sad. Children and teens may also complain of headaches and/or stomachaches when no physical cause can be found.

Symptoms of a manic episode may include:

- Feelings of euphoria, abnormal excitement, or elevated mood
- Talking very rapidly or excessively
- Needing less sleep than normal, yet still having plenty of energy
- Feeling agitated, irritable, hyper, or easily distracted
- Engaging in risky behavior such as lavish spending, impulsive sexual encounters, or ill-advised business decisions

The Mood Disorder Questionnaire

Answer each of the following questions to the best of your ability and share with your health care provider.

(Caregivers should answer with their loved one’s symptoms and behaviors in mind and share with their health care provider.)

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?  
   Yes  No

   ...you were so irritable that you shouted at people or started fights or arguments?  
   Yes  No

   ...you felt much more self-confident than usual?  
   Yes  No

   ...you got much less sleep than usual and found you didn’t really miss it?  
   Yes  No

   ...you were much more talkative or spoke much faster than usual?  
   Yes  No

   ...thoughts raced through your head or you couldn’t slow your mind down?  
   Yes  No

   ...you were so easily distracted by things around you that you had trouble concentrating or staying on track?  
   Yes  No

   ...you had much more energy than usual?  
   Yes  No

   ...you were much more active or did many more things than usual?  
   Yes  No

   ...you were much more social or outgoing than usual, for example, you telephoned friends in the middle of the night?  
   Yes  No

   ...you were much more interested in sex than usual?  
   Yes  No

   ...you did things that were unusual for you or that other people might have thought were excessive, foolish, or risky?  
   Yes  No

   ...spending money got you or your family into trouble?  
   Yes  No

Please see Important Safety Information, including Boxed Warning, at LATUDA.com.
The Mood Disorder Questionnaire

Continued from page 7

2. If you checked YES to more than one of the questions on the previous page, have several of these ever happened during the same period of time?

| Yes | No |

3. How much of a problem did any of these cause you—like being unable to work; having family, money, or legal troubles; getting into arguments or fights?

| No problem | Minor problem | Moderate problem | Serious problem |

The Mood Disorder Questionnaire is appropriate for use with adults aged 18 and older.
This instrument is designed for screening purposes only and is not to be used as a diagnostic tool. Always consult with your health care provider.


Bipolar depression may be difficult to diagnose

If a person with bipolar disorder sees a doctor while depressed, a previous experience of mania may be overlooked or forgotten, leading to a misdiagnosis of major depressive disorder. That’s why it’s important to mention any manic episodes, no matter how far in the past they occurred.

Adding to the difficulties, in children and teens, manic symptoms may be misdiagnosed as attention-deficit/hyperactivity disorder (ADHD). However, it is also common that ADHD and bipolar disorder co-occur.

Family history is also important, as it is one of the strongest and most consistent risk factors for bipolar disorder. Let your doctor know if someone else in your family has bipolar disorder or another mental illness.

If you have thoughts about suicide, call your health care provider right away or go to the emergency room. You can also call the National Suicide Prevention Lifeline 24 hours a day at 1-800-273-TALK (8255).

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

Please see additional Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.

Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).
What is Latuda® (lurasidone HCl)?

LATUDA is a once-a-day prescription medicine. It is approved to treat bipolar depression in adults, and in children and teens (10 to 17 years) on its own. LATUDA is also approved to treat bipolar depression in adults taking lithium or valproate.

How to take LATUDA
Please take LATUDA exactly as directed by your health care provider, and talk to him or her if you have any questions about how to take LATUDA.
LATUDA should be taken with food—at least 350 calories. Taking LATUDA with food can help your body absorb the medicine.

What to expect with LATUDA
Everyone responds to medication differently. LATUDA and many medicines like it work gradually, so it may take some time to notice improvements. It is important to take your medication as directed by your health care provider.
Learning about the possible side effects of LATUDA is an important part of taking your medication. Knowing as much as you can about LATUDA can help you and your health care provider make informed decisions, and may help you stick to your treatment plan.
LATUDA can cause serious side effects. Please see Important Safety Information on pages 32–35 and the enclosed Medication Guide for a complete list.

IMPORTANT SAFETY INFORMATION
FOR Latuda® (lurasidone HCl)

LATUDA may cause serious side effects, including:
• 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.

Please see additional Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.
Frequently asked questions about Latuda® (lurasidone HCl)

What are the most common side effects of LATUDA?
The most common side effects of LATUDA include:
- 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 health care provider if you are not sure if you are taking any of these medicines

How long should LATUDA be taken?
Only your health care provider should advise which medications you should take, and for how long.

Talking to your health care provider about Latuda® (lurasidone HCl)

Maybe you or a loved one was recently diagnosed with bipolar depression—or maybe you’re considering asking your health care provider about a change to your treatment plan. Either way, this guide can help you prepare for your next appointment.
- What are the benefits of LATUDA?
- What are the risks of LATUDA? How safe is it?
- Can you tell me about the clinical study data on weight?
- What if I’m pregnant or planning to become pregnant?
- What side effects should I look out for?
- Could LATUDA be right for me in addition to my current medication(s)?

Other things I’d like to know about LATUDA:

Please see Important Safety Information, including Boxed Warning, at LATUDA.com.

Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).
Additional talking points for your appointment
Sharing as much information as you can may help your doctor create a treatment plan that works best for you. The following information is a good place to start:

• Symptoms
• Prior diagnosis
• Family history
• Current treatments
• Treatment goals

Other things I want to share with my doctor:

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What to remember when taking Latuda® (lurasidone HCl)

- **Stick with it**—don’t stop or change your dose without talking to your doctor.
- **Keep cool and drink plenty of water.** Your body may not be able to control your temperature as effectively when taking LATUDA.
- **Stay away from alcohol.** It may make side effects worse.
- **Skip the grapefruit and grapefruit juice.** They can affect the amount of LATUDA in your blood.
- **Take LATUDA with food—at least 350 calories.** Food can help your body absorb LATUDA.
- **Watch out for drowsiness.** Until you get used to LATUDA, don’t get behind the wheel or take part in any dangerous activities.
- **Reach out for help if your symptoms get worse.** Be sure to tell your doctor if your symptoms get worse after starting LATUDA.
- **Remember to take LATUDA once a day.** Once-daily LATUDA should always be taken exactly as it is prescribed for you by your doctor.

**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.
  - **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

Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).

Please see additional Important Safety Information, including **Boxed Warning**, on pages 32–35 and enclosed Medication Guide.
It’s hard enough having bipolar depression. When your doctor prescribes Latuda® (lurasidone HCl), Sunovion Answers is here to provide services to support you. It can be found at LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).

Here’s what Sunovion Answers brings you:

- **LATUDA Copay Savings Card**: Pay as little as a $15* copay per month
- **Reimbursement Specialists**: Call for help with insurance coverage, copay, and benefit concerns
- **Sunovion Answers via email**: Insights and information for where you are in your treatment
- **Doctor Discussion Guide**: A guide to getting what you need from your next doctor’s appointment
- **Mood Disorder Questionnaire**: Complete a questionnaire to help your doctor screen for bipolar disorder
- **Daily Mood Monitor**: Track how you’re feeling daily to create a chart to review with your doctor
- **Patient Stories**: Real stories about people living with bipolar depression
- **Organizations That May Help**: Get support catered to your personal needs with support groups that can help

Many of these benefits are freely available. To take full advantage of all that Sunovion Answers has to offer—simply sign up. Go to LATUDA.com or call 1-855-5LATUDA (1-855-552-8832). Available anytime between 8 AM–12 midnight (ET).

*Check your eligibility and sign up at LATUDA.com or call 1-855-5LATUDA. Exclusions may apply.

**Could LATUDA be right for you? Fill out the Discussion Guide on pages 13 and 14, and then tear it off and take it to your next doctor’s appointment.**

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

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 32–35 and enclosed Medication Guide.
Making copays more affordable with the Latuda® (lurasidone HCl) Copay Savings Card

With LATUDA, you may pay as little as a $15* copay per month. Sign up at LATUDA.com.

Follow these steps to save on your prescription when using a mail-order pharmacy:

1. After receiving your prescription in the mail, either call 1-855-5LATUDA (1-855-552-8832) or go online directly to McKesson’s rebate portal at patientrebateonline.com.
   — Be sure to have your LATUDA Copay Savings Card, prescription, and mailing information ready.

2. A prepopulated, customized rebate form will be sent to you. Mail this form along with a copy of your pharmacy receipt or invoice to McKesson and receive your rebate check!

Repeat these steps each time you reorder your prescription to receive your rebate in the mail.

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 32–35 and enclosed Medication Guide.

If you’re eligible, you may pay as little as a $15* copay each month for up to 12 prescriptions.* Show your LATUDA Copay Savings Card at the pharmacy each time you fill or refill your prescription, and you’re on your way to savings.

* Check your eligibility and sign up at LATUDA.com or call 1-855-5LATUDA. Maximum benefit of $400 for a 30-day prescription fill.

Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).
Tips for living well with bipolar depression

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

• Try to find more time to spend with family and friends
• Remember that a healthy diet is good for you not only physically, but also mentally and emotionally
• Try to find something to be grateful for every single day
• Try to go to bed at the same time every night. This may help you maintain a regular sleep schedule
• Exercise may help you feel good about yourself. Even a short walk outside can make a difference
• Try to plan for the possible. Focusing on what you can do instead of what you can’t do is a good start
• Make a list of what you’d like to accomplish in your daily routine
• Remember to always reach out to your health care provider if you feel that you can’t manage on your own

IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)

LATUDA may cause serious side effects, including:

• 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)

Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).

Please see additional Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.
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 between people living with bipolar depression and those who care about them. Your support team includes your health care providers, 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 in their field; however, you are the expert when it comes to you and your treatment goals. You should always feel comfortable communicating your symptoms, feelings, and needs.

There are a number of health care providers who may coordinate your care to help you manage your bipolar depression. Each may play a different role in the diagnosis and treatment of bipolar disorder, so it’s important that you communicate with each of them and understand how they communicate with each other about your treatment plan and goals.

- **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 health care provider who specializes in diagnosing and treating diseases of the brain, emotional disturbance, and behavior issues; can treat patients with talk therapy; cannot prescribe medication
- **Social worker or counselor/therapist:** A trained professional who specializes in thought- and action-related coping skills; can treat patients with talk therapy; cannot prescribe medication
- **General practitioner (GP):** A physician whose practice is not limited to a specific branch of medicine or class of diseases; can prescribe medication
- **Pediatrician:** A physician who specializes in the medical care of infants, children, and adolescents; can prescribe medicine

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

Please see additional Important Safety Information, including **Boxed Warning**, on pages 32–35 and enclosed Medication Guide.
Supporting a loved one with bipolar depression

Treatment, such as Latuda® (lurasidone HCl), may help your loved one manage symptoms; however, living with someone with bipolar disorder can still be a challenge.

As a member of their support team and a partner in your loved one’s care, you play a vital role in helping your loved one manage bipolar depression. You are someone they can trust, rely on for support, and help make important treatment decisions.

Keep important details close
Support your loved one by being ready in case of an emergency. You should have easy access to the following contact details and information:

• Your loved one’s health care provider and pharmacy
• Their medications and dosage
• Their insurance
• Bipolar depression hotline and support groups

Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).

Get and stay involved in medical decisions

Along with your loved one and their doctor, you are part of the support team. If helping to make important medical decisions is part of your responsibility, your loved one may need to sign a release so the doctor can share medical information with you.

Let the doctor know about any side effects or changes in behavior
Since you may notice things that your loved one may not—like changes in mood or behavior—stay alert to changes and have an open discussion with your loved one and their doctor. Download the helpful Daily Mood Monitor on LATUDA.com.

Sunovion Answers for LATUDA is for you, too
Sunovion Answers for LATUDA is designed to support your loved one’s treatment. Your role in helping them with their treatment could make a difference in their success too. That’s why Sunovion Answers is also focused on helping you. Learn more on pages 16 and 17, and visit LATUDA.com to discover all the resources available to you and your loved one.

IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)

LATUDA may cause serious side effects, including:
• 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 32–35 and enclosed Medication Guide.
Help your loved one stay on their medication

Latuda® (lurasidone HCl) is taken once a day with food—at least 350 calories. Taking LATUDA with food can help the body absorb the medicine.

Everyone responds to medication differently. Many medications prescribed for bipolar depression work gradually, so it may take some time to notice improvements.

For this reason, it’s important for your loved one to take LATUDA exactly as prescribed, and to not stop taking LATUDA without speaking to their health care provider. You should encourage your loved one to visit a health care provider regularly.

Daily reminders, gentle encouragement, and possibly keeping a journal or calendar can really help your loved one stay on track.

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 32–35 and enclosed Medication Guide.
Caring for a child with bipolar depression

Learning that your child has bipolar depression can be difficult. You may worry about what this means for your child, or feel isolated and unsure of what to do. Educating yourself about your child’s condition can not only help you deal with your feelings, it can also empower you to be your child’s best advocate.

Some ways you can support your child are to:

• Talk—and listen—to your child about their illness. Create an open and ongoing conversation to reassure your child and to let them know how much you care about them

• Focus on the positive and the possible. Encourage constructive self-expression and reward your child’s positive behaviors

• Establish and maintain a daily routine. Setting and sticking to a schedule can help minimize stress

• Keep a mood diary. Tracking your child’s symptoms can help you identify patterns of behavior and possible triggers

• Build a support system. Team up with friends, family, teachers, health care professionals, and communicate often to support your child’s treatment plan

• Be prepared for emergencies. Have a crisis plan in place and identify support team members who can help follow the plan in case of an emergency

When your child has bipolar depression, it can also take a toll on the whole family. It’s important to recognize this impact early so you can meet your family’s needs and reduce any conflict or stress.

Tips for nurturing siblings:

• Let them know that it’s okay to feel angry, jealous, or sad

• Foster positive self-expression and coping skills

• Encourage involvement in family therapy or individual therapy

• Watch for signs of distress, and be aware they may hide their struggles

• Spend one-on-one time with siblings and be available to talk openly and honestly about their feelings

Tips to sustain your marriage or partnership:

• Make a conscious effort to prioritize your relationship

• Try to express respect and gratitude every day

• Consider marriage counseling to support your efforts

• Be solution oriented—don’t dwell on what’s wrong, instead focus on how you can work toward what you want

• Take a team approach to caregiving so that you can give each other a break and help avoid burnout

IMPORTANT SAFETY INFORMATION FOR Latuda® (lurasidone HCl)

LATUDA may cause serious side effects, including:

• 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

Please see additional Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.
Caregivers should care for themselves, too

Whether you are a parent, a family member, or a friend caring for someone with bipolar depression, it can affect you, too. It is important to take care of yourself so you can be there for your loved one when they need you. Here are some things that can help:

- Exercise and eat a healthy diet
- Get enough rest
- Prioritize to avoid feeling overwhelmed
- Take a break—even an afternoon nap may help

- Stay connected and get support—joining a support group can help your mental health
- Trust yourself. Believing that you can handle the stress of being a caregiver will help you do just that
- To ease stress, establish a future plan for your friend or loved one’s care should you no longer be able to act as caregiver
- Share the responsibility, if possible. Shifting the responsibility from one person to the entire family or support team can help encourage a sense of team involvement, and a “we’re in this together” attitude

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
- Difficulty swallowing

Please see additional Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.
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 32–35 and enclosed Medication Guide.
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

Visit LATUDA.com or call 1-855-5LATUDA (1-855-552-8832).

PLEASE SEE ENCLOSED MEDICATION GUIDE.

- 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 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 additional Important Safety Information, including Boxed Warning, on pages 32–35 and enclosed Medication Guide.
Making copays more affordable.*

See page 18 to learn how you may save on your copay for LATUDA prescriptions and refills.

*Exclusions may apply.

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