



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.

A CONVERSATION WORTH HAVING WITH YOUR DOCTOR

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



Please see additional Important Safety Information about LATUDA, including **Boxed Warning**, below and on the next page, and full Prescribing Information, including the Medication Guide, at LATUDA.com.

Let's start: 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.



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



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



What challenges are keeping you from reaching your treatment goals?



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

Talk to your doctor: Ask if LATUDA could make a real difference in your bipolar depression symptoms.



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.

Wondering how much LATUDA costs? **Most pay \$0-\$8.95** for a 30-tablet prescription

Visit LATUDA.com for cost and copay savings options. Exclusions may apply.

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.

Do not take LATUDA if you are allergic to LATUDA or any of the ingredients in LATUDA or if you are taking certain other medicines called CYP3A4 inhibitors or inducers. The most common side effects of LATUDA in adults with bipolar depression were restlessness, difficult or slow movement, and sleepiness or drowsiness. In children (10-17 years) with bipolar depression, they were nausea, weight gain, and problems sleeping. These are not all of the possible side effects of LATUDA. **For more information, refer to the next page, visit LATUDA.com, or talk to your doctor.**

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.

Information for Patients About

Latuda® (lurasidone HCl) tablets

(lurasidone HCl) tablets

This summary does not include all information about LATUDA and is not meant to take the place of discussions with your healthcare provider about your treatment. Please read this important information carefully before you start taking LATUDA. Discuss any questions about LATUDA with your healthcare provider.

What is the most important information I should know about LATUDA?

Serious side effects may happen when you take LATUDA, 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 for some children and young adults 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. Some people may have a much higher risk of 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 your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call between visits as needed, especially if you have concerns about symptoms.

Call your 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 or 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); or other unusual changes in behavior or mood.

What is LATUDA?

LATUDA is a prescription medicine used:

- 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 10 years of age with bipolar depression.

Who should not take LATUDA?

Do not take LATUDA if you are:

- allergic to lurasidone hydrochloride or any of the ingredients in LATUDA below:
 - **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.
- 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 whether you take these medicines.

What should I tell my healthcare provider before taking LATUDA?

Before you take LATUDA, tell your healthcare provider about all 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-research-programs/pregnancyregistry/>.
- are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into breast milk. Talk to your healthcare provider about the best way to feed your baby while you take LATUDA.

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

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

What should I avoid while taking LATUDA?

- Do not drive, operate 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 may affect the amount of LATUDA in your blood.
- Avoid getting overheated or dehydrated while you take LATUDA. Do not over-exercise. 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.** Stroke can lead to death.
- **Neuroleptic malignant syndrome (NMS).** NMS is a serious condition that can lead to death. Call your healthcare provider or get emergency medical treatment right away if you have some or all of the following signs and symptoms of NMS: high fever; stiff muscles; confusion; increased sweating; or changes in your breathing, heart rate, or 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 while you take LATUDA.

Call your healthcare provider if you have any of these symptoms of high blood sugar while you take 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 while you take LATUDA.
- **Increased prolactin levels in your blood (hyperprolactinemia).** Your healthcare provider may do blood tests to check your prolactin levels while you take LATUDA. Tell your healthcare 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 not breastfeeding. **Males** – problems getting or maintaining an erection (erectile dysfunction); or enlargement of breasts (gynecomastia).
- **Low white blood cell count.** Your healthcare provider may do blood tests during the first few months you take 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. These side effects 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) for 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.**

The most common side effects of LATUDA include:

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

These are not all the possible side effects of LATUDA. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LATUDA.

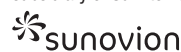
Medicines are sometimes prescribed for purposes other than those listed in this summary. Do not take LATUDA for a condition where it was not prescribed. Do not give LATUDA to other people, even if they have the same symptoms you have. It may harm them.

This information is not comprehensive.

How to get more information:

- Talk to your healthcare provider or pharmacist.
- Visit www.LATUDA.com to obtain the FDA-approved product labeling.
- Call Sunovion at 1-888-394-7377.


LATUDA is a registered trademark of Sumitomo Dainippon Pharma Co. Ltd. Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co. Ltd.



Manufactured for: Sunovion Pharmaceuticals Inc.
Marlborough, MA 01752 USA

©2020 Sunovion Pharmaceuticals Inc. All rights reserved.
May 2020 LAT-US-00258-20



LATUDA, SUNOVION, and  are registered trademarks of Sumitomo Dainippon Pharma Co., Ltd. Sunovion Pharmaceuticals Inc. is a U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd. ©2020 Sunovion Pharmaceuticals Inc. All rights reserved. 10/20 LAT-US-00398-20

