

Medication Guide
LATUDA (luh-TOO-duh)
(lurasidone hydrochloride)
Tablets

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

LATUDA may cause serious side effects, including:

- 1. Increased risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis).** Medicines like LATUDA can increase the risk of death in elderly people who are confused, have memory loss and have lost touch with reality (dementia-related psychosis). LATUDA should not be used to treat people with dementia-related psychosis.
- 2. Increased risk of suicidal thoughts or actions (antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions).**
 - **Talk to your, or your family member's, healthcare provider about:**
 - all risks and benefits of treatment with antidepressant medicines.
 - all treatment choices for depression or other serious mental illness.
 - **Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.**
 - **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 the 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 the 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 else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to your healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.
- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child's healthcare provider for more information.

What is LATUDA?

LATUDA is a prescription medicine used to treat adults with:

- schizophrenia
- depressive episodes associated with bipolar I disorder, alone or with lithium or valproate

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

Who should not take LATUDA?

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.

- 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 healthcare provider if you are not sure if you are taking any of these medicines.

What should I tell my healthcare provider before taking LATUDA?

Before you take LATUDA, tell your healthcare provider if you:

- have or have had diabetes or high blood sugar in you or your family. Your healthcare provider should check your blood sugar before you start LATUDA and also during therapy.
- have or have had high levels of total cholesterol, triglycerides or LDL-cholesterol or low levels of HDL-cholesterol
- have or have had low or high blood pressure
- have or have had low white blood cell count
- have or have had seizures
- have or have had abnormal thyroid tests
- have or have had high prolactin levels
- have or have had heart problems
- have or have had liver problems
- have or have had any other medical conditions
- are pregnant or plan to become pregnant. It is not known if LATUDA will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into your breast milk. You and your healthcare provider should decide if you will take LATUDA or breastfeed. You should not do both.

Tell the healthcare provider about all the medicines that you take or recently have taken including prescription medicines, over-the-counter medicines, herbal supplements and vitamins.

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

Especially tell your healthcare provider if you take or plan to take medicines for:

- depression
- high blood pressure
- Parkinson's disease
- trouble sleeping
- abnormal heart beats or rhythm
- epilepsy
- inflammation
- psychosis

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 yourself.
- Take LATUDA by mouth, with food (at least 350 calories).
- If you take too much LATUDA, call your healthcare provider or poison control center at 1-800-222-1222 right away, or go to the nearest hospital emergency room.

What should I avoid while taking LATUDA?

- Avoid eating grapefruit or drinking grapefruit juice while you take LATUDA since these can affect the amount of LATUDA in the blood. Do not drive, operate machinery, or do other dangerous activities until you know how LATUDA affects you. LATUDA may make you drowsy.
- Avoid getting overheated or dehydrated.
 - 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 or heavy clothing.
 - Drink plenty of water.
- Do not drink alcohol while taking LATUDA. It may make some side effects of LATUDA worse.

What are possible side effects of LATUDA?

LATUDA can cause serious side effects, including:

- **See “What is the most important information I should know about LATUDA?”**
- **stroke that can lead to death can happen in elderly people with dementia who take medicines like LATUDA**
- **neuroleptic malignant syndrome (NMS)**. NMS is a rare but very serious condition that can happen in people who take antipsychotic medicines, including LATUDA. NMS can cause death and must be treated in a hospital. Call your healthcare provider right away if you become severely ill and have some or all of these symptoms:
 - high fever
 - excessive sweating
 - rigid muscles
 - confusion
 - changes in your breathing, heartbeat, and blood pressure
- **movements you cannot control in your face, tongue, or other body parts (tardive dyskinesia)**. These may be signs of a serious condition. Tardive dyskinesia may not go away, even if you stop taking LATUDA. Tardive dyskinesia may also start after you stop taking LATUDA.

- **high blood sugar (hyperglycemia).** High blood sugar can happen if you have diabetes already or if you have never had diabetes. High blood sugar could lead to:
 - build-up of acid in your blood due to ketones (ketoacidosis)
 - coma
 - death

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 LATUDA and during therapy.

Call your healthcare 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
- **high fat levels in your blood (increased cholesterol and triglycerides).** High fat levels may happen in people treated with LATUDA. You may not have any symptoms, so your healthcare provider may decide to check your cholesterol and triglycerides during your treatment with LATUDA.
 - **increase in weight (weight gain).** Weight gain has been reported in patients taking medicines like LATUDA. You and your healthcare provider should check your weight regularly. Talk to your healthcare provider about ways to control weight gain, such as eating a healthy, balanced diet, and exercising.
 - **increases in prolactin levels.** Your healthcare provider may do blood tests to check your prolactin levels.
 - **low white blood cell count**
 - **decreased blood pressure (orthostatic hypotension),** including lightheadedness or fainting caused by a sudden change in heart rate and blood pressure when rising too quickly from a sitting or lying position.
 - **seizures**
 - **difficulty swallowing**

The most common side effects of LATUDA include:

- sleepiness or drowsiness
- restlessness and feeling like you need to move around (akathisia)
- difficulty moving, slow movements, muscle stiffness, or tremor
- nausea

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

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 you have. It may harm them.

This Medication Guide summarizes the most important information about LATUDA. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about LATUDA that is written for health professionals.

For more information, go to www.LATUDA.com or call 1-888-394-7377.

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

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

Manufactured for:

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