

Please see Important Safety Information, including **Boxed Warning**, on the next page.



Things to Know When Taking LATUDA

When Taking LATUDA You Should...

Follow the below directions and keep talking to your doctor.



Stick with it.

Be patient. For some people, LATUDA may work gradually.



Keep cool and stay hydrated.

Your temperature may fluctuate when taking LATUDA.



Stay away from alcohol.

Alcohol may worsen any side effects.



Say "NO" to grapefruit.

Grapefruit can affect the amount of LATUDA in your blood.



Eat at least 350 calories.

Food can help your body absorb LATUDA.



Watch out for drowsiness.

It may take time to get used to LATUDA. Be careful when operating machinery.



Ask for help.

Talk to your doctor if symptoms worsen.



Take LATUDA once a day.

Take LATUDA as your doctor prescribes.

IMPORTANT SAFETY INFORMATION AND INDICATIONS 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.

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: great 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.

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
 - o Tell your health care provider if you become pregnant or think you are pregnant during treatment with LATUDA
 - o 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 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)