

Things to Know When Taking LATUDA

How to take once-daily LATUDA

Your healthcare professional will take great care in determining the right bipolar depression medication dose for you. Be sure to take LATUDA exactly as prescribed by your doctor. If you have any questions about your dosage or how to take LATUDA, don't hesitate to ask.



Stick with it. Everyone responds to medication differently. LATUDA may work gradually, so it may take some time to notice improvements.



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. Talk to your doctor before stopping LATUDA or changing your dose.

IMPORTANT SAFETY INFORMATION AND INDICATIONS FOR LATUDA

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

Elderly patients with dementia-related psychosis (having lost touch with reality due to confusion and memory loss) treated with this type of medicine are at an increased risk of death compared to patients receiving placebo (sugar pill). LATUDA is not approved for treating elderly patients with dementia-related psychosis.

Antidepressants have increased the risk of suicidal thoughts and actions in some children, teenagers, and young adults. Patients of all ages starting treatment should be watched closely for worsening of depression, suicidal thoughts or actions, unusual changes in behavior, agitation, and irritability. Patients, families, and caregivers should 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. Report any change in these symptoms immediately to the doctor. LATUDA is not approved for patients under the age of 18 years.

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

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LATUDA can cause serious side effects, including stroke that can lead to death, which can happen in elderly people with dementia who take medicines like LATUDA.

Neuroleptic malignant syndrome (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, or changes in your breathing, heartbeat, or blood pressure.

Tardive dyskinesia (TD) is a serious and sometimes permanent side effect reported with LATUDA and similar medicines. Tell your doctor about any movements you cannot control in your face, tongue, or other body parts, as they may be signs of TD. TD may not go away, even if you stop taking LATUDA. TD may also start after you stop taking LATUDA.

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.

Increases in triglycerides and LDL (bad) cholesterol and decreases in HDL (good) cholesterol have been reported 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.

Some patients may gain weight while taking LATUDA. Your doctor should check your weight regularly.

Tell your doctor if you experience any of these:

- feeling dizzy or light-headed upon standing,
- decreases in white blood cells (which can be fatal),
- trouble swallowing.

LATUDA and medicines like it may raise the level of prolactin. Tell your healthcare provider if you experience a lack of menstrual periods, leaking or enlarged breasts, or impotence.

Tell your healthcare provider if you have a seizure disorder, have had seizures in the past, or have conditions that increase your risk for seizures.

Tell your healthcare provider if you experience prolonged, abnormal muscle spasms or contractions, which may be a sign of a condition called dystonia.

LATUDA can affect your judgment, thinking, and motor skills. You should not drive or operate hazardous machinery until you know how LATUDA affects you.

LATUDA may make you more sensitive to heat. You may have trouble cooling off. Be careful when exercising or when doing things likely to cause dehydration or make you warm.

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

Tell your healthcare provider about all prescription and over-the-counter medicines you are taking or plan to take, since there are some risks for drug interactions with LATUDA. Tell your healthcare provider if you are allergic to any of the ingredients of LATUDA or take certain medications called CYP3A4 inhibitors or inducers. Ask your healthcare provider if you are not sure if you are taking any of these medications.

Avoid drinking alcohol while taking LATUDA.

Tell your healthcare provider if you are pregnant or if you are planning to get pregnant. Avoid breastfeeding while taking LATUDA.

The most common side effects of LATUDA include sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor; and nausea.

These are not all the possible side effects of LATUDA. For more information, ask your healthcare 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 used to treat adult patients with:

- Depressive episodes in bipolar I disorder (bipolar depression) when used alone or with lithium or valproate
- Schizophrenia

