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[Home](#) → [Drugs, Herbs and Supplements](#) → Lurasidone

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## Lurasidone

pronounced as (loo ras' I done )

### IMPORTANT WARNING:

Important warning for older adults with dementia:

Studies have shown that older adults with dementia (a brain disorder that affects the ability to remember, think clearly, communicate, and perform daily activities and that may cause changes in mood and personality) who take antipsychotics (medications for mental illness) such as lurasidone have an increased chance of death during treatment. Older adults with dementia may also have a greater chance of having a stroke or ministroke during treatment with antipsychotics.

Lurasidone is not approved by the Food and Drug Administration (FDA) for the treatment of behavior disorders in older adults with dementia. Talk to the doctor who prescribed this medication if you, a family member, or someone you care for has dementia and is taking lurasidone. For more information visit the FDA website: <http://www.fda.gov/Drugs> [<http://www.fda.gov/Drugs>]

Important warning for people who have depression:

A small number of children, teenagers, and young adults (up to 24 years of age) who took medications for depression during clinical studies became suicidal (thinking about harming or killing oneself or planning or trying to do so). Children, teenagers, and young adults who take antidepressants to treat depression or other mental illnesses may be more likely to become suicidal than children, teenagers, and young adults who do not take antidepressants to treat these conditions. However, experts are not sure about how great this risk is and how much it should be considered in deciding whether a child or teenager should take an antidepressant. Children younger than 10 years of age should not normally take lurasidone to treat depression, but in some cases, a doctor may decide that lurasidone is the best medication to treat a child's condition.

You should know that your mental health may change in unexpected ways when you take lurasidone to treat depression or other mental illness even if you are an adult over 24 years of age. You may become suicidal, especially at the beginning of your treatment and any time that your dose is increased or decreased. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression; thinking about harming or killing yourself, or planning or trying to do so; extreme worry; agitation; panic attacks; difficulty falling asleep or staying asleep; aggressive behavior; irritability; acting without thinking;

severe restlessness; and frenzied abnormal excitement. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.

Your healthcare provider will want to see you often while you are taking lurasidone, especially at the beginning of your treatment. Be sure to keep all appointments for office visits with your doctor.

No matter what your age, before you take an antidepressant, you, your family, or your caregiver should talk to your doctor about the risks and benefits of treating your condition with an antidepressant or with other treatments. You should also talk about the risks and benefits of not treating your condition. You should know that having depression or another mental illness greatly increases the risk that you will become suicidal. This risk is higher if you or anyone in your family has or has ever had bipolar disorder (mood that changes from depressed to abnormally excited) or mania or has thought about or attempted suicide. Talk to your doctor about your condition, symptoms, and personal and family medical history. You and your doctor will decide what type of treatment is right for you.

## Why is this medication prescribed?

Lurasidone is used to treat the symptoms of schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions) in adults and children 13 years of age and older. It is also used to treat depression in adults and children 10 years of age and older with bipolar disorder (manic depressive disorder; a disease that causes episodes of depression, episodes of mania, and other abnormal moods). Lurasidone is also used along with lithium (Lithobid) or valproate (Depacon) to treat depression in adults with bipolar disorder. Lurasidone is in a class of medications called atypical antipsychotics. It works by changing the activity of certain natural substances in the brain.

## How should this medicine be used?

Lurasidone comes as a tablet to take by mouth. It is usually taken with a meal (at least 350 calories) once a day. Take lurasidone at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take lurasidone exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Lurasidone controls schizophrenia and depression in people with bipolar disorder but it does not cure these conditions. It may take several weeks or longer before you feel the full benefit of lurasidone. Continue to take lurasidone even if you feel well. Do not stop taking lurasidone without talking to your doctor.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking lurasidone,

- tell your doctor and pharmacist if you are allergic to lurasidone, any other medications, or any of the ingredients in lurasidone tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor if you are taking carbamazepine (Carbatrol, Epitol, Tegretol); clarithromycin (Biaxin, in Prevpac); ketoconazole; mibefradil; phenytoin (Dilantin, Phenytek); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); ritonavir (Norvir); St. John's wort; or voriconazole (Vfend). Your doctor will probably tell you not to take lurasidone if you are taking either of these medications.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: antidepressants; antihistamines; atazanavir (Reyataz); bosentan (Tracleer); diltiazem (Cardizem, Cartia, Taztia, Tiazac, others); efavirenz (Sustiva, in Atripla); erythromycin (E.E.S., E-Mycin, Ery-Tab, others); etravirine (Intelence); fluconazole (Diflucan); indinavir (Crixivan); ipratropium (Atrovent, in Combivent, in Duoneb); itraconazole (Sporanox); medications to control anxiety, sedatives, sleeping pills, or tranquilizers; medications to control blood pressure; medications for glaucoma, inflammatory bowel disease, motion sickness, myasthenia gravis, Parkinson's disease, ulcers, or urinary problems; modafinil (Provigil); nafcillin; nefazodone; nelfinavir (Viracept); phenobarbital; pioglitazone (Actos, in Duetact, in Actoplus Met); rifabutin (Mycobutin); or verapamil (Calan, Verelan, others, in Tarka); Other medications may also interact with lurasidone, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you use or have ever used street drugs or have overused prescription medications and if you have or have ever had a stroke; a ministroke (TIA); chest pain, heart disease, or a heart attack; an irregular heartbeat; heart failure; Parkinson's disease (a disorder of the nervous system that causes difficulties with movement, muscle control, and balance); Alzheimer's disease (a brain disease that slowly destroys the memory and ability to think, learn, communicate and handle daily activities); seizures; dementia; breast cancer; trouble keeping your balance; any condition that makes it difficult for you to swallow; high or low blood pressure; high prolactin levels; a high level of fats (cholesterol and triglycerides) in your blood; a low number of white blood cells; kidney disease; liver disease; high blood sugar; or if you or anyone in your family has or has ever had diabetes. Tell your doctor if you have severe vomiting or diarrhea or signs of dehydration now, or if you develop these symptoms at any time during your treatment. Also tell your doctor if you have ever had to stop taking a medication for mental illness because of severe side effects.
- tell your doctor if you are pregnant, especially if you are in the last few months of your pregnancy, or if you plan to become pregnant or are breastfeeding. If you become pregnant while taking lurasidone, call your doctor. Lurasidone may cause problems in newborns following delivery if it is taken during the last months of pregnancy.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking lurasidone.
- you should know that lurasidone may make you drowsy. Do not drive a car or operate hazardous machinery until you know how this medication affects you.
- you should know that you may experience hyperglycemia (increases in your blood sugar) while you are taking this medication, even if you do not already have diabetes. If you have schizophrenia, you are more likely to develop diabetes than people who do not have schizophrenia, and taking lurasidone or similar medications may increase this risk. Tell your doctor immediately if you have any of the following symptoms while you are taking lurasidone: extreme thirst, frequent urination, extreme hunger, blurred vision, or weakness. It is very important to call your doctor as soon as you have any of these symptoms, because high blood sugar can cause a serious condition called ketoacidosis.

Ketoacidosis may become life-threatening if it is not treated at an early stage. Symptoms of ketoacidosis include dry mouth, nausea and vomiting, shortness of breath, breath that smells fruity, and decreased consciousness.

- you should know that lurasidone may cause dizziness, lightheadedness, and fainting when you get up too quickly from a lying position. This is more common when you first start taking lurasidone. To help avoid this problem, get out of bed slowly, resting your feet on the floor for a few minutes before standing up.
- you should know that lurasidone may make it harder for your body to cool down when it gets very hot. Tell your doctor if you plan to exercise or be exposed to extreme heat.
- you should know that lurasidone may cause an increase in weight. It is important to have your weight checked periodically while you are taking this medication.

## **What special dietary instructions should I follow?**

Do not eat large amounts of grapefruit or drink grapefruit juice while taking this medication.

## **What should I do if I forget a dose?**

Take the missed dose with food (at least 350 calories) as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## **What side effects can this medication cause?**

**Lurasidone may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- dizziness, feeling unsteady, or having trouble keeping your balance
- anxiety
- weakness
- tiredness
- restlessness
- uncontrollable shaking of a part of the body
- slow movements or shuffling walk
- nausea
- vomiting
- appetite changes
- increased saliva
- breast enlargement or discharge
- late or missed menstrual period
- decreased sexual ability

**Some side effects can be serious. If you experience any of these symptoms, or those listed in the IMPORTANT WARNINGS and SPECIAL PRECAUTIONS sections, call your doctor immediately:**

- seizures
- swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs
- hoarseness
- difficulty swallowing or breathing
- shortness of breath
- abnormal heartbeat
- sore throat, fever, cough, chills, and other signs of infection
- fever, sweating, confusion, fast or irregular heartbeat, and severe muscle stiffness
- unusual movements of your face or body that you cannot control
- falling

Lurasidone may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## **What should I know about storage and disposal of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## **In case of emergency/overdose**

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor may order certain lab tests to check your body's response to lurasidone.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Latuda®

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