



PATIENT & CAREGIVER EDUCATION

Olanzapine and Samidorphan

This information from Lexicomp® explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Lybalvi

Warning

- There is a higher chance of death in older adults who take this drug for mental problems caused by dementia. Most of the deaths were linked to heart disease or infection. This drug is not approved to treat mental problems caused by dementia.

What is this drug used for?

- It is used to treat bipolar disorder.
- It is used to treat schizophrenia.
- It may be given to you for other reasons. Talk with the

doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have taken an opioid drug like morphine or oxycodone in the past 14 days, or if you are having withdrawal signs.
- If you are taking any of these drugs: Carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, or St. John's wort.
- If you are taking levodopa.
- If you are taking another drug that has the same drug in it.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- To lower the chance of feeling dizzy or passing out, rise slowly if you have been sitting or lying down. Be careful going up and down stairs.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- This drug may affect certain lab tests. Be sure your doctor and lab workers know you use this drug.
- High blood sugar or diabetes, high cholesterol, and weight gain have happened with drugs like this one. These may raise the chance of heart and brain blood vessel disease.
- Check your blood sugar as you have been told by your doctor.
- Be careful in hot weather or while being active. Drink lots of fluids to stop fluid loss.

- Avoid drinking alcohol while taking this drug.
- Talk with your doctor before you use marijuana, other forms of cannabis, or prescription or OTC drugs that may slow your actions.
- Dizziness, sleepiness, and feeling less stable may happen with this drug. These may lead to falling, which can cause broken bones or other health problems.
- If you have opioid use disorder and are given this drug, you may have signs of opioid withdrawal. Some of these signs are sweating, shaking, fever, chills, diarrhea, upset stomach, throwing up, stomach cramps, goosebumps, body aches, anxiety, feeling irritable, yawning, or fast heartbeat.
- Do not take opioid drugs while you are taking this drug. Opioid drugs will not work. Do not take more opioid drugs to try to get them to work. Doing this may cause severe injury, coma, or death.
- Do not take an opioid drug for at least 5 days after stopping this drug. People who took opioid drugs on a regular basis before taking this drug may get more effects from opioid drugs when this drug is stopped. Taking opioid drugs in the amount used before may raise the risk of opioid overdose. If you think there has been an opioid overdose, get medical care right away. If

you have questions, talk with your doctor.

- Older adults with dementia taking drugs like this one have had a higher number of strokes. Sometimes these have been deadly. This drug is not approved to treat mental problems caused by dementia.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may affect being able to get pregnant. This effect goes back to normal when the drug is stopped. If you have questions, talk with the doctor.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.
- Taking this drug in the third trimester of pregnancy may lead to side effects or withdrawal in the newborn.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever;

wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.

- Signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Trouble controlling body movements, twitching, change in balance, trouble swallowing or speaking.
- Severe dizziness or passing out.
- Fast, slow, or abnormal heartbeat.
- Not sweating during activities or in warm temperatures.
- Seizures.
- Feeling confused.
- Memory problems or loss.
- Chest pain.
- A burning, numbness, or tingling feeling that is not normal.
- Swollen gland.
- Trouble passing urine.
- Dark urine or yellow skin or eyes.
- Shortness of breath, a big weight gain, or swelling in the arms or legs.

- Enlarged breasts, nipple discharge, not able to get or keep an erection, or menstrual changes.
- Low white blood cell counts have happened with this drug. This may lead to a higher chance of getting an infection. Call your doctor right away if you have signs of infection like fever, chills, or sore throat.
- Some people may get a severe muscle problem called tardive dyskinesia. This problem may lessen or go away after stopping this drug, but it may not go away. The risk is greater with diabetes and in older adults, especially older females. The risk is greater with longer use or higher doses, but it may also occur after short-term use with low doses. Call your doctor right away if you have trouble controlling body movements or problems with your tongue, face, mouth, or jaw like tongue sticking out, puffing cheeks, mouth puckering, or chewing.
- A very bad and sometimes deadly health problem called neuroleptic malignant syndrome (NMS) may happen. Call your doctor right away if you have any fever, muscle cramps or stiffness, dizziness, very bad headache, confusion, change in thinking, fast heartbeat, heartbeat that does not feel normal, or are sweating a lot.
- A severe and sometimes deadly reaction has happened. Most of the time, this reaction has signs like fever, rash, or swollen glands with problems in body organs like the

liver, kidney, blood, heart, muscles and joints, or lungs. If you have questions, talk with the doctor.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Feeling dizzy, sleepy, tired, or weak.
- Shakiness.
- Headache.
- Constipation.
- Dry mouth.
- Weight gain.
- Increased appetite.
- Back pain.
- More saliva.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at <https://www.fda.gov/medwatch>.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Take with or without food.
- Swallow this drug whole.
- Do not split or break tablet.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Drink lots of noncaffeine liquids unless told to drink less liquid by your doctor.
- If you start or stop smoking, talk with your doctor. How much drug you take may need to be changed.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next shot, skip the missed shot and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store tablets in the original container at room temperature. Keep the cap tightly closed. Do not take out the antimoisture cube or packet.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each

time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.

- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a

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Last Reviewed Date

2026-02-06

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

Olanzapine and Samidorphan - Last updated on December 12, 2022
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