

LATUDA FILM-COATED TABLETS

Lurasidone hydrochloride (20mg, 40mg & 80mg)

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What Latuda is used for

LATUDA is a prescription medicine used:

- To treat adult and adolescent patients 13 to 17 years of age and older with schizophrenia.
- Alone to treat adult and adolescent patients 13 to 17 years of age and older with major depressive episodes associated with Bipolar I Disorder (bipolar depression).
- With the medicine lithium or valproate to treat adults with major depressive episodes associated with Bipolar I Disorder (bipolar depression).

How Latuda works

LATUDA works by adjusting the levels of certain chemical messengers, called neurotransmitters, in the brain.

Before you use Latuda

- When you must not use it

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.
- 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 doctor or pharmacist if you are not sure if you are taking any of these medicines.

Children and adolescents

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

- less than 13 years of age

with schizophrenia.

- less than 13 years of age with bipolar depression.
- for the treatment of irritability associated with autistic disorder.

- Before you start to use it

Tell your doctor or pharmacist 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 are at a risk of having diabetes (e.g. being overweight or a family history of diabetes). Your doctor should check your blood sugar before you start taking LATUDA and regularly during treatment.
- 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

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you:

- are pregnant or plan to become pregnant. It is not known if LATUDA will harm your unborn baby. Talk to your doctor or pharmacist about the risk to your unborn baby if you take LATUDA during pregnancy. Tell your doctor or pharmacist if you become pregnant or think you are pregnant during treatment with LATUDA.
- are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into your breast milk. Talk to your doctor or pharmacist about the best way to feed your baby during treatment with LATUDA.

- Taking other medicines

Tell your doctor or pharmacist 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 doctor or pharmacist 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 doctor or pharmacist first.

Know the medicines you take. Keep a list of your medicines to show your doctor or pharmacist when you get a new medicine.

How to use Latuda

- How much to use

Take LATUDA exactly as your doctor or pharmacist tells you to take it. Do not change the dose or stop taking LATUDA without first talking to your doctor or pharmacist.

- When to use it

Take LATUDA by mouth, with food (at least 350 calories).

- How long to use it

Do not stop using Latuda unless your doctor tells you to stop taking it.

- If you forget to use it

If you miss a dose of LATUDA, take it as soon as you remember. If you are close to your next dose, skip the missed dose and just take your next dose at your regular time. Do not take 2 doses at the same time. If you are not sure about your dosing, call your doctor.

- If you use too much (overdose)

If you take too much LATUDA, call your doctor or pharmacist or poison control center or go to the nearest hospital emergency room right away.

While you are using Latuda

- Things you must do

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

- Things you must not do

Do not drive, operate heavy

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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 during treatment with LATUDA. Grapefruit and grapefruit juice may affect the amount of LATUDA in your blood.

- Things to be careful of

- 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.

Side effects

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) a serious condition that can lead to death. Call your doctor or pharmacist 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
- confusion
- changes in your breathing, heart rate, and blood pressure
- stiff muscles
- increased sweating

- 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.

Call your doctor or pharmacist if you have any of these symptoms of high blood sugar during treatment with LATUDA:

- Feel very thirsty
- Feel very hungry
- Feel sick to your stomach
- Need to urinate more than usual
- Feel weak or tired
- Feel confused, or your breath smells fruity
- increased fat levels (cholesterol and triglycerides) in your blood.
- weight gain. You and your doctor or pharmacist should check your weight regularly during treatment with LATUDA.

- Increased prolactin levels in your blood (hyperprolactinemia). Your doctor or pharmacist may do blood tests to check your prolactin levels during treatment with LATUDA. Tell your doctor or pharmacist if you have any of the following signs and symptoms of hyperprolactinemia:

Females:

- absence of your menstrual cycle
- secretion of breast milk when you are not breastfeeding

Males:

- problems getting or maintaining an erection (erectile dysfunction)
- enlargement of breasts (gynecomastia)

- Low white blood cell count. Your doctor or pharmacist 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).

- Disruption of the body's ability to reduce core body temperature.

- Mania or Hypomania (manic episodes) in people with a history of bipolar disorder. Symptoms may include:

- Greatly increased energy
- Racing thoughts
- Unusually grand ideas
- Talking more or faster than usual
- Severe problems sleeping
- Reckless behavior
- Excessive happiness or irritability

- Difficulty swallowing.

Talk to your doctor or pharmacist if you experience:

- Unpleasant leg sensations and an intense urge to move the legs (restless legs syndrome)
- Trouble breathing during sleep (sleep apnoea)
- Difficulty or inability to pass urine (urinary retention)

The most common side effects of LATUDA include:

- Adults with schizophrenia:
 - sleepiness or drowsiness
 - restlessness and feeling like you need to move around (akathisia)
 - difficulty moving, slow movements, muscle stiffness, or tremor
 - nausea
- Adolescent 13 to 17 years of age with schizophrenia:
 - sleepiness or drowsiness
 - nausea
 - restlessness and feeling like you need to move around (akathisia)
 - difficulty moving, slow movements, muscle stiffness, or tremor
 - runny nose
 - vomiting
- Adults with bipolar depression:
 - restlessness and feeling like you need to move around (akathisia)
 - difficulty moving, slow

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- movements, muscle stiffness, or tremor
- sleepiness or drowsiness

- Adolescent 13 to 17 years of age with bipolar depression:
 - nausea
 - weight gain
 - problems sleeping (insomnia)

These are not all of the possible side effects of LATUDA. Call your doctor for medical advice about side effects.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Latuda

- Storage

Store LATUDA below 30°C.

Keep LATUDA and all medicines out of the reach of children.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Latuda Film-Coated Tablets 20mg: White to off-white, round film-coated tablet, debossed with "L 20"

Latuda Film-Coated Tablets 40mg: White to off-white, round film-coated tablet, debossed with "L 40"

- **Latuda Film-Coated Tablets 80mg:** Pale green, oval film-coated tablet, debossed with "L 80"

- Ingredients

- **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.

- MAL Number

- Latuda Film-Coated Tablets 20mg – MAL22126001ACRZ
- Latuda Film-Coated Tablets 40mg – MAL22126002ACRZ
- Latuda Film-Coated Tablets 80mg – MAL22126003ACRZ

Manufacturer

Bushu Pharmaceuticals Ltd
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JAPAN

Product Registration Holder

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Product Owner

Sumitomo Pharma Co., Ltd.

Date of Revision

02 October 2025

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