MEDICATION GUIDE
LATUDA (luh-TOO-duh)
(lurasidone hydrochloride)
tablets

What is the most important information I should know about LATUDA?

LATUDA may cause serious side effects, including:

- **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.
- **Increased risk of suicidal thoughts or actions in children and young adults.** Antidepressant medicines may increase suicidal thoughts or actions in some children and young adults within the first few months of treatment and when the dose is changed.
  - o **Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions.** These include people who have (or have a family history of) depression, bipolar illness (also called manic-depressive illness), or a history of suicidal thoughts or actions.

How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?

- o 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.
- o Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- o Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- new or worse depression
- feeling very agitated or restless
- trouble sleeping (insomnia)
- acting aggressive, being angry, or violent
- an extreme increase in activity and talking (mania)
- attempts to commit suicide
- new or worse anxiety
- panic attacks
- new or worse irritability
- acting on dangerous impulses
- other unusual changes in behavior or mood

What is LATUDA?

LATUDA is a prescription medicine used:

- To treat people 13 years of age or older with schizophrenia.
- Alone to treat people 10 years of age and older 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).

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

- less than13 years of age with schizophrenia
- less than 10 years of age with bipolar depression
- for the treatment of irritability associated with autistic disorder

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 healthcare provider if you are not sure if you are taking any of these medicines.

Before taking LATUDA, tell your healthcare 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 healthcare provider about the risk to your unborn baby if you take LATUDA during pregnancy.
  - Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with LATUDA.
  - If you become pregnant during treatment with LATUDA, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling 1-866-961-2388 or go to http://womensmentalhealth.org/clinical-and-researchprograms/pregnancyregistry/.
- are breastfeeding or plan to breastfeed. It is not known if LATUDA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with LATUDA.

Tell your healthcare 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 healthcare 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 healthcare provider first.

Know the medicines you take. Keep a list of your medicines to show your healthcare provider and pharmacist when you get a new medicine.

How should I take LATUDA?

- Take LATUDA exactly as your healthcare provider tells you to take it. Do not change the dose or stop taking LATUDA without first talking to your healthcare provider.
- Take LATUDA by mouth, with food (at least 350 calories).
- If you take too much LATUDA, call your healthcare provider or poison control center or go to the nearest hospital emergency room right away.

What should I avoid while taking LATUDA?

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

What are the possible side effects of LATUDA?

LATUDA may cause serious side effects, including:

- **See "What is the most important information I should know about LATUDA?"**
- **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 healthcare 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
  - 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. 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 and during treatment with LATUDA.

    Call your healthcare provider 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 healthcare provider should check your weight regularly during treatment with LATUDA.
- **Increased prolactin levels in your blood (hyperprolactinemia).** Your healthcare provider may do blood tests to check your prolactin levels during treatment with LATUDA. Tell your healthcare provider 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 healthcare 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.** See "What should I avoid while taking LATUDA?"
- **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**

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

- **Children 10 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 side effects to FDA at 1-800-FDA-1088.

How should I store LATUDA?

- Store LATUDA tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep LATUDA and all medicines out of the reach of children.

General information about the safe and effective use of LATUDA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use LATUDA for a condition for which it was not prescribed. Do not give LATUDA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about LATUDA that is written for health professionals.

What are the ingredients in LATUDA?

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

Manufactured for: Sunovion Pharmaceuticals Inc. Marlborough, MA 01752 USA

For more information, go to www.LATUDA.com or call 1-888-394-7377.

This Medication Guide has been approved by the U.S. Food and Drug Administration Revised: 3/2018