Putting it together:
A guide to LATUDA for schizophrenia in adults and adolescents

*13 to 17 years.

Please see Important Safety Information, including Boxed Warnings, on pages 15–17 and enclosed Medication Guide.
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Actor portrayal

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What is schizophrenia?

Schizophrenia is a serious brain disorder that affects how a person thinks, acts, and perceives reality. If you are diagnosed with schizophrenia, it’s important to know that you are not alone. Schizophrenia affects more than 2 million Americans. While there is currently no cure for schizophrenia, the symptoms of schizophrenia may be managed with proper treatment.

The cause of schizophrenia is not known, but it is thought that a person’s genes (family history), biology (brain chemistry and structure), and environment (birth trauma, viruses, stressors) may all play a part in this complex disease.

Schizophrenia symptoms usually start between ages 16 and 30. Males tend to experience symptoms a little earlier than females.

Schizophrenia symptoms can be separated into 2 general groups. Positive symptoms are exaggerated or irrational traits or behaviors. Negative symptoms reflect an absence of certain traits or behaviors.

Positive symptoms may include:

- Hallucinations (hearing voices or seeing things that are not there)
- Delusions (believing things that are not real or true)
- Disorganized speech and behavior (difficulty organizing thoughts, remembering things, or keeping several ideas in mind at the same time)

Negative symptoms may include:

- Limited emotional expression (hard to show emotion)
- A lack of motivation (hard to start and follow through with activities)
- Limited thought and speech (not talkative)
- No longer getting pleasure out of or having interest in life activities
Schizophrenia can be difficult to recognize in teens

While the symptoms are the same as those seen in adults, they often come on more gradually for teenagers. Some early signs of schizophrenia may include:

- A drop in school performance
- Withdrawal from friends or family
- Irritability or depression
- Lack of motivation
- Difficulty sleeping
- Odd or strange behavior

Sometimes it can be tough to tell the difference between normal teenage moodiness and signs of something more serious. But recognizing symptoms early can go a long way toward managing a lifelong condition like schizophrenia.

IMPORTANT SAFETY INFORMATION FOR LATUDA

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

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.

Antidepressant medicines may increase suicidal thoughts or behaviors in some children, teenagers, and young adults within the first few months of treatment and when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Patients on antidepressants and their families or caregivers should watch for new or worsening depression symptoms, 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.

For more information visit LATUDA.com.
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Managing schizophrenia with medication

One of the ways to manage the symptoms of schizophrenia is to take prescription medicines called antipsychotics. These medicines have been helpful in relieving the symptoms of schizophrenia.

For many people, taking medicine usually goes along with other supportive therapy like counseling or joining a support group. It is important to take your medication as prescribed by a doctor, but striving toward daily living goals like going to work or school and maintaining personal relationships is just as important.

Managing schizophrenia is a team effort, so you should stay involved with a doctor, psychologist, social worker, nurses, family and friends, and anyone else who is involved in helping your recovery. Here are ways to help you stay on track with your medication:

• **Take your medicine as prescribed by your doctor.** It is important not to skip doses of your medicine.

• **Create reminders.** Remembering to take medicine every day can be a challenge. Reminders that might help you to stay on track include making checklists, putting up reminder signs around your home, or having a friend or family member remind you. Mobile apps may also be helpful with sending reminders.

• **Talk with your doctor—promptly—about side effects.** If you experience bothersome side effects, talk to your doctor before you stop taking your medication. While not all side effects can be eliminated or reduced, many can. A change in dose level or medication may be needed.
Other ways you and your caregiver can help manage schizophrenia

• Make healthy lifestyle choices. Managing your schizophrenia is about more than taking medication. Your general health can affect your mental health and vice versa. It is important for you to eat right, exercise, and avoid substances that can make your health worse, such as tobacco, alcohol, and illegal drugs. If you’re concerned about substance abuse, there are people you can talk to, including your doctor.

• Join a support group. Getting involved with established support groups can be a great way to share experiences with, and get advice from, people who are going through the same things.

• Keep family and friends involved in your life. Staying involved with loved ones can help you cope with the stress you may feel while managing your illness. Remember, when it comes to managing schizophrenia, there’s no such thing as too much support.

• Participate in activities that you enjoy. Sharing experiences with others and doing things that you enjoy may help you manage your illness and positively influence your recovery.

IMPORTANT SAFETY INFORMATION FOR LATUDA
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) is a serious condition that can lead to death. Call your health care 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, increased sweating, stiff muscles, confusion, or changes in your breathing, heart rate, and blood pressure

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What is LATUDA?

LATUDA is a once-a-day oral prescription medicine that may help keep the symptoms of schizophrenia under control. It has been approved for the treatment of schizophrenia in people 13 years of age or older.

LATUDA was evaluated in many studies of adults living with schizophrenia and in one study of adolescents 13–17 years of age. These studies looked at how well LATUDA works, how safe it is, and how well people tolerated it.

Medications for schizophrenia work differently in each person, so be sure you and your caregiver talk with your doctor if you have any questions about your dose or how you should be taking LATUDA. Together, you, your doctor, and your caregiver can decide what’s working best to help manage your illness and whether a change in your plan of care is needed.

For more information about LATUDA, please call 1-855-5LATUDA (1-855-552-8832) or visit LATUDA.com.

IMPORTANT SAFETY INFORMATION FOR LATUDA

LATUDA may cause serious side effects, including:
• 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
How does LATUDA work?

LATUDA is part of a class of medicines called atypical antipsychotics. Atypical antipsychotics are thought to work by adjusting the levels of certain chemical messengers, called neurotransmitters, in the brain.

Neurotransmitters are chemicals in the brain that allow nerve cells, or neurons, to transmit a signal and communicate with each other. Two important neurotransmitters in the brain are dopamine and serotonin. One theory for why people experience schizophrenia symptoms is that there is too much or too little dopamine in some areas of the brain.

It is not known exactly how LATUDA works, and the exact way antipsychotics work is unknown. But LATUDA is thought to work by adjusting the effect of dopamine and serotonin in the brain.

### IMPORTANT SAFETY INFORMATION FOR LATUDA

LATUDA may cause serious side effects, including:

- **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 health care provider should check your blood sugar before you start and during treatment with LATUDA.
  - Call your health care 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.

For more information visit LATUDA.com. Please see additional Important Safety Information, including Boxed Warnings, on pages 15–17 and enclosed Medication Guide.
What to remember when taking LATUDA

Stick with it—don’t stop or change your dose without talking to your doctor.

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.

Avoid 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.
A partner on your treatment journey, and ongoing support

The journey to wellness can be complex and overwhelming, but there are resources and support available to help you along the way. When your doctor prescribes LATUDA, Sunovion Answers is here to provide services to support you.

A Sunovion Answers Support Specialist will provide you with copay assistance, help understanding insurance coverage, product information, and additional resource information.

Call Sunovion Answers to speak to a support specialist at 1-855-5-LATUDA (1-855-552-8832) anytime between 8 AM and 12 midnight (ET), Monday through Friday, or visit LATUDA.com/answers.

Pay as little as a $15* copay per month for LATUDA

If you’re eligible, the LATUDA Copay Savings Card may lower your copay to as little as a $15* copay per month on up to 12 monthly prescription fills in a calendar year—saving you up to $125* each fill. Simply show your LATUDA Copay Savings Card at the pharmacy when you fill or refill your prescription.

Check your eligibility and sign up at LATUDA.com or call 1-855-5-LATUDA.

*Restrictions apply.

IMPORTANT SAFETY INFORMATION FOR LATUDA

LATUDA may cause serious side effects, including:

- Problems with your metabolism such as:
  - Increased fat levels (cholesterol and triglycerides) in your blood
  - Weight gain. You and your health care provider should check your weight regularly during treatment with LATUDA

For more information visit LATUDA.com.

Please see additional Important Safety Information, including Boxed Warnings, on pages 15–17 and enclosed Medication Guide.
Information for caregivers

It can be a very challenging experience to have a family member or friend diagnosed with schizophrenia. It can be especially hard if they act and talk differently than they have in the past. You may feel unsure how to react, which may lead to feelings of guilt, helplessness, fear, or anger. Learning more about schizophrenia may not only help you deal with your feelings, but may also help your loved one. **If your loved one has been diagnosed with schizophrenia, you can take steps to help them:**

- **Stay on track with medication.** It is very important that the person you support takes his or her medicine as prescribed. One of the possible symptoms of schizophrenia is a “lack of insight”—people living with schizophrenia may not even be aware that they have it. So they may not think they need to take any medication.

  Daily reminders, gentle encouragement, and possibly keeping a journal or calendar can really help your loved one stay on track.

- **Feel encouraged and supported.** Help the person you care for set goals he or she can achieve, such as engaging in social activities every day with other friends and family. It may be hard for your loved one to meet all the expectations that you both had before schizophrenia entered your lives. Be positive and try not to pressure or criticize your loved one, as stress may lead to a worsening of symptoms.
• **Stay engaged in daily activities.** One of your big challenges might be finding ways to support and protect the person living with schizophrenia while allowing room for self-reliance. Rather than doing everything for your loved one, encourage them to do some routine activities of daily living for themselves, like making a meal or doing household chores. You can also encourage them to pursue favorite interests, like reading, painting, or visiting friends.

• **Eat healthy foods.** Having a well-balanced diet is always important. Encourage healthy eating and offer nutritious foods and snacks whenever possible.

• **Communicate and socialize.** It may be hard to talk to someone living with schizophrenia at times. But doing something together doesn’t always require talking. Going for a walk or playing a game may be a stress-free way to spend time together.

Your family member or friend living with schizophrenia may sometimes want to share thoughts or feelings with you but they don’t make sense to you. Be patient. Try not to correct your loved one, but listen attentively and offer your perspective.

**If your loved one is having serious thoughts about suicide, call their health care provider or take them to the emergency room.**

They can also call the National Suicide Prevention Lifeline 24 hours a day at 1-800-273-8255.

**IMPORTANT SAFETY INFORMATION FOR LATUDA**

**LATUDA may cause serious side effects, including:**

**Problems with your metabolism such as:**

• **Increased prolactin levels in your blood (hyperprolactinemia).** Your health care provider may do blood tests to check your prolactin levels during treatment with LATUDA. Tell your health care provider if you have any of the following signs and symptoms of hyperprolactinemia:
  – **Females:** absence of your menstrual cycle or secretion of breast milk when you are not breastfeeding
  – **Males:** problems getting or maintaining an erection (erectic dysfunction) or enlargement of breasts (gynecomastia)

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Learning about schizophrenia is an important part of your plan of care. Not only can the following resources help you find out more about schizophrenia and its treatment, but they can be a great way to share knowledge and common experiences.

**Crisis Text Line**
crisistextline.org
Text HELLO to 741-741 from anywhere in the USA, anytime, about any type of crisis.

**American Psychiatric Association**
psychiatry.org/patients-families

**The Jed Foundation (JED)**
JedFoundation.org  1-212-647-7544

**Mental Health America (MHA)**
mentalhealthamerica.net  1-800-969-6642

**National Alliance on Mental Illness (NAMI)**
nami.org  1-800-950-6264

**National Institute of Mental Health (NIMH)**
nimh.nih.gov  1-866-615-6464

**National Suicide Prevention Lifeline**
suicidepreventionlifeline.org
1-800-273-TALK (8255) 24-hour national crisis hotline
IMPORTANT SAFETY INFORMATION AND INDICATIONS FOR LATUDA

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- **Females:** absence of your menstrual cycle or secretion of breast milk when you are not breastfeeding
- **Males:** problems getting or maintaining an erection (erectile dysfunction) or enlargement of breasts (gynecomastia)

Low white blood cell count. Your health care 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. 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.

Mania or hypomania (manic episodes) in people with a history of bipolar disorder. Symptoms may include: greatly increased energy, severe problems sleeping, racing thoughts, reckless behavior, unusually grand ideas, excessive happiness or irritability, or talking more or faster than usual.

Difficulty swallowing.

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 while you take LATUDA since these can affect the amount of LATUDA in the blood.

Do not take LATUDA if you are allergic to any of the ingredients in LATUDA or take certain medications called CYP3A4 inhibitors or inducers. Ask your health care provider if you are not sure if you are taking any of these medications.

Tell your health care 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 health care 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 health care provider first.

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

The most common side effects of LATUDA include:
• Adults with schizophrenia: sleepiness or drowsiness; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, or muscle stiffness; and nausea
• Adolescents (13 to 17 years) with schizophrenia: sleepiness or drowsiness; nausea; restlessness or feeling like you need to move around (akathisia); difficulty moving, slow movements, muscle stiffness, or tremor; runny nose/nasal inflammation; and vomiting
• Adults with bipolar depression: restlessness or feeling like you need to move around (akathisia); difficulty moving or slow movements; and sleepiness or drowsiness
• Children (10 to 17 years) with bipolar depression: nausea; weight gain; and problems sleeping (insomnia)

These are not all the possible side effects of LATUDA. For more information, ask your health care 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 a prescription medicine used:
• To treat adults and adolescents (13 to 17 years) with schizophrenia
• Alone to treat adults, children and teens (10 to 17 years) 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)
Making copays more affordable.*

See page 11 to learn how you may save on a LATUDA prescription.

*Exclusions may apply.