

To apply for help in affording your **LATUDA**[®] (lurasidone HCI) prescription, please see Important Safety Information on pages 4 and 5 and enclosed full Prescribing Information, and provide information below.

Please mail completed application to:

Sunovion Support[®] Prescription Assistance Program ("Program") PO Box 220285, Charlotte, NC 28222-0285

or fax: (877) 850-0821

Remember to include both your signature and that of your prescribing doctor, proof of income and the patient's prescription. If you have any questions or need help filling out this form, please contact us at (877) 850-0819 or visit <u>www.sunovionsupport.com</u>.

| Patient Information | | |
|---|--------|-------------|
| Name: | | |
| Date of Birth: Phone: () | | Gender: M F |
| Mailing Address: | | |
| City: | State: | ZIP: |
| Is the patient a US resident (includes Puerto Rico)? YES NO | | |
| Is the patient 18 years of age or older? YES NO | | |

If Patient is a minor, under the age of 18 years, or has a legal guardian please complete this section:

| Parents/Legal Guardian(s) Name: | | |
|---------------------------------|--------|------|
| Phone: | | |
| Mailing Address: | | |
| City: | State: | ZIP: |

Household Income Information (if patient is under the age of 18, please complete information as the legal guardian)

- 1. Number of people in household: _____ (include yourself, your spouse and any dependents)
- 2. What is total **GROSS ANNUAL** household income (including Social Security, Disability, Veterans, Wages, pension benefits, etc.)? \$_____
- 3. Did the patient/guardian file a Federal Income Tax Return for previous calendar year? YES NO

Please provide us with one of the following items to show total gross annual household income:

- Current paycheck stubs, proof of Social Security Income, 1099 or W-2 forms for all members of household
- Federal Income Tax Return (IRS Form 1040 or 1040EZ) for prior tax year

If the patient has not filed a Federal Income Tax Return, visit <u>www.IRS.gov</u> to request a free Verification of Non-Filing. Click on "Order a Transcript" or call (800) 908-9946. Use IRS Form 4506-T and check box 7 to request verification of non-filing.

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Patient's Insurance Information

| 1. Is the patient enrolled in Medicare/Medicaid? | YES | NO |
|--|-----|----|
|--|-----|----|

| 2. Does the patient have prescription drug coverage through any other benefit program that | helps pay for prescription |
|--|----------------------------|
| medicine, such as private insurance or VA or military benefits, including Medicare Part D? | YES NO |

If yes: please describe: _____

From the Healthcare Professional (to be completed by the doctor who is prescribing the medicine)

| *Healthcare Professional: | |
|--|--|
| HCCE permit # (required in state of FL only) | |
| Site contact: State | e License #: |
| Facility Name: Tax | ID #: |
| Phone: () Fax: (|) |
| Street address: | |
| City: | State: Zip: |
| Prescription Information: Latuda (Iurasidone HCI) | |
| Please see Important Safety Information, including Boxed Warning on pages 4 and 3 | 5 and enclosed full Prescribing Information. |
| Dosage: 20mg/day 40mg/day 60mg/day 80mg/day | 120mg/day 160mg/day |
| Day Supply: 🔄 30 Days 📄 60 Days 📄 90 days | |
| Method of delivery: | |
| Prescription to be shipped directly to healthcare professional's add | dress provided on page 3 |
| Patient will pick up prescription at retail pharmacy (will receive 30 | |
| Number of Refills (max 11): | |
| If there is a change in prescription or diagnosis of patient, Sunovion Support ne | eeds to be notified in writing. |
| ICD-10 Code (required information) F20.0 Paranoid schizophrenia F20.1 Disorganized schizophrenia F20.3 Undifferentiated schizophrenia F20.5 Residual schizophrenia F20.9 Other schizophrenia F20.9 Schizophrenia, unspecified F31.30 Bipolar disorder, current episode depressed, mild or moderat F31.31 Bipolar disorder, current episode depressed, moderate F31.4 Bipolar disorder, current episode depressed, severe, without p | |

* If Healthcare Provider is not an MD please provide required supporting documentation authorizing prescribing of and receiving of prescription medication. Please visit the website www. NABP.net if you have questions as to what your state may require for you to receive medication shipped directly to you. All required documentation must be received to ship medication.



Your Consent is Required to Process Application for the Sunovion Support Prescription Assistance Program

I acknowledge and agree that the above information is complete and accurate. I attest that I have no prescription insurance coverage, including Medicaid, Medicare or other public or private program, and I have insufficient financial resources to pay for the prescribed product. I understand and acknowledge that this assistance is temporary and that this program may be changed or discontinued at any time without notice.

| Patient's Signature: | Date: |
|--|------------|
| If you are unable to sign or are a minor, under the age of 18, a parent or legal guardian must | also sign. |
| Representative's Name: | |
| Representative's Signature: | Date: |
| Describe relationship to Applicant: | |

Healthcare Professional Signature is Required to Process Application for the Sunovion Support Prescription Assistance Program

My signature below certifies that the person named in this form is my patient and medication received from the Program is only for that patient's use as indicated by the US Food and Drug Administration, and the information provided, to my knowledge, is accurate. I understand this Program is only for LATUDA and it will not be offered for sale, trade, or barter. I agree that I will not submit any claim for reimbursement concerning the Product to Medicaid, Medicare, or any other third party, or return such Product for credit. I also agree that the Program has the right at any time to contact my patient, to modify or terminate the Program, and to recall or discontinue Product without notice. To the best of my knowledge, my patient does not have prescription drug insurance coverage (including Medicaid, Medicare, or other public or private programs) for the product being requested.

Letter of Affiliation: I certify that I (a) am affiliated with the entity(ies) and location(s) identified on this application, (b) will be responsible in all respects for the receipt and accountability of the pharmaceutical products shipped to this entity at such location, and (c) will immediately notify the Program if either of the foregoing statements is no longer true.

Please indicate affiliated shipping address for healthcare professional to whom the medication will be shipped:

| Healthcare Professional Name: | | | | |
|------------------------------------|--------|------|------------|--|
| Street Address: | | | | |
| City: | State: | Zip: | Phone: () | |
| Healthcare Professional Signature: | | | Date: | |

California residents, please visit <u>www.sunovion.com/CAprivacynotice</u> for information about the collection and use of your personal information.

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Important Safety Information and indications 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.

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
- 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 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
 - · 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
- 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 (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 <u>www.fda.gov/medwatch</u> 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)

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Authorization and Consent to Share and Disclose Health Information with the Sunovion Support Prescription Assistance Program ("Program")

Please read and sign this form so that you or the person for whom you are assisting may be able to participate in the Program. Please note "I" is defined as the potential Participant.

- I acknowledge and agree that all the information I provide in connection with my application to the Program will be used to decide if I qualify for the Program.
- By signing below, I verify that the information on my application, including a copy of my proof of income documentation, is complete and accurate.
- I do not have any other coverage for prescription medications, including Medicaid, Medicare, or any public or private assistance programs or any other prescription insurance.
- I understand that any changes to my financial, prescription drug coverage, diagnosis, or insurance information may affect whether I am able to continue to participate in the Program. I agree to contact the Program to inform them of any changes to my income, prescription drug coverage, diagnosis, or insurance information.
- I allow my health care provider(s), my pharmacy(ies), and my health plan or insurers, to give medical information relating to my use or need for product(s) provided under the Program to The Lash Group, Inc. The Lash Group runs the Program on behalf of Sunovion Pharmaceuticals Inc. My medical information can include spoken or written facts about my health and payment benefits. It can include copies of records from my health care provider, pharmacy, or health plan about my health or health care.
- People who work for The Lash Group and the Program may see my information, but they may use it only to help me get assistance to
 receive my Sunovion medication, to determine whether I qualify for the Program, to operate the Program, or as otherwise required or
 permitted by law.
- I allow The Lash Group and the Program the right to verify and to evaluate any financial documentation, insurance information, and medical records submitted to the Program to determine if I qualify for the Program and to operate the Program.
- I understand that The Lash Group and the Program have the right to contact me directly to confirm receipt of medications [or to obtain my feedback about the Program] and that the Program can revise, change, or terminate the Program at any time.
- I understand that I may cancel my permission and withdraw from this Program at any time.
- I understand that if I cancel my permission I can tell my health care provider, my pharmacy, and my insurer in writing that I do not want them to share any more information with The Lash Group and the Program, but it will not change any actions they took before I told them and it will terminate my participation in the Program.
- This authorization and consent will last for up to 6 months.
- I know that I have a right to see or copy the information my health care providers, my pharmacy, or insurers have given to The Lash Group and the Program.
- I understand that I am free at any time to switch my health care provider and it will not affect eligibility for financial assistance. This Program is offered to me regardless of any health care provider or pharmacy I use.
- I KNOW THAT I MAY REFUSE TO SIGN THIS FORM. My choice about whether to sign this form will not change the way my health care providers, pharmacies, or insurers treat me. If I refuse to sign this form, I know that this means I will not be eligible to participate in the Program.
- I understand that signature of a legal guardian or parent is required for all minor applicants and those patients who are unable to sign.

| Applicant Signature: | Date: |
|---|---|
| Applicant Name: | |
| If you are unable to sign or are a minor, under the age of 18, a part | rent or legal guardian must also sign. |
| Representative's Name: | Date: |
| Representative's Signature: | Describe relationship to Applicant: |
| If someone helped you with the application and you want them to | answer questions for you, please give us their name and phone number: |
| Name: | Phone: () |

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Please remove the following fax number(s) from future faxes _

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