

Would you like to increase your understanding of and confidence in prescribing a treatment option for your adult patients with schizophrenia?



## LATUDA Exploration: Discover Another Option for the Treatment of Schizophrenia Evening Symposium

Increase your understanding of LATUDA • Gain confidence in prescribing LATUDA

Please see Important Safety Information, including **Boxed Warning**, about LATUDA® (lurasidone HCl) tablets on reverse side and enclosed full Prescribing Information.

### Program Overview

Treating schizophrenia with antipsychotics is not a “one-size-fits-all” proposition. Individual responses to medications differ markedly. This promotional, non-CME program is intended for healthcare professionals who are involved in the treatment of adult patients with schizophrenia.

This therapeutic awareness program will provide the mental health care community with a thorough understanding of another treatment option for adult patients with schizophrenia.

- Stephen M. Stahl, MD, PhD or other **expert faculty** will guide participants through explorations of the indication and usage, clinical pharmacology, efficacy data, and safety and tolerability profile of LATUDA.
- The program will include a plenary lecture featuring animations and quizzes to engage the audience and **bring the scientific story to life**.
- This session will be followed by an immersive learning experience: participants will rotate between **activity stations** that will test their knowledge of LATUDA. The multimedia sessions will **spark an educational and competitive yet fun atmosphere** through games, real-life case studies, and a poster “scavenger hunt.”

With the information presented in this program, clinicians may obtain greater insight into whether LATUDA is appropriate for the treatment of their adult patients living with schizophrenia. Clinicians now have another therapeutic option when considering the treatment needs of their patients with schizophrenia.

### Program Learning Objectives

- To introduce LATUDA and discuss the following:
  - Indication and usage
  - Clinical pharmacology
  - Efficacy
  - Safety and tolerability profile
- To test knowledge of LATUDA through interactive learning stations (games, case studies, and poster session)

### Agenda *(Pre-registration required)*

#### Description

Registration and Dinner

6:00-6:30 PM

#### Lecture:

LATUDA Exploration:

Discover Another Option for the Treatment of Schizophrenia

#### Q&A

LATUDA Poster Session  
“Scavenger Hunt”

#### Real-Life Case Studies


#### Tournament of Treatment:


LATUDA Pyramid Challenge and  
LATUDA Wheel of Discovery

#### Closing

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 **Latuda**<sup>®</sup>  
(lurasidone HCl) tablets  
40mg and 80mg

 **SUNOVION**

## INDICATIONS AND USAGE

LATUDA is indicated for the treatment of patients with schizophrenia. Efficacy was established in four 6-week controlled studies of adult patients with schizophrenia. The effectiveness of LATUDA for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use LATUDA for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

## IMPORTANT SAFETY INFORMATION FOR LATUDA

### WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Analyses of 17 placebo-controlled trials (modal duration of 10 weeks), largely in patients taking atypical antipsychotic drugs, revealed a risk of death in the drug-treated patients of between 1.6 to 1.7 times that seen in placebo-treated patients. Over the course of a typical 10-week controlled trial, the rate of death in drug-treated patients was about 4.5% compared to a rate of about 2.6% in the placebo group. Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. LATUDA is not approved for the treatment of patients with dementia-related psychosis.

## CONTRAINDICATIONS

LATUDA is contraindicated in any patient with a known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone. LATUDA is contraindicated with strong CYP3A4 inhibitors (e.g., ketoconazole) and strong CYP3A4 inducers (e.g., rifampin).

## WARNINGS AND PRECAUTIONS

**Cerebrovascular Adverse Reactions, Including Stroke:** In placebo-controlled trials with risperidone, aripiprazole, and olanzapine in elderly subjects with dementia, there was a higher incidence of cerebrovascular adverse reactions (cerebrovascular accidents and transient ischemic attacks) including fatalities compared to placebo-treated subjects. LATUDA is not approved for the treatment of patients with dementia-related psychosis.

**Neuroleptic Malignant Syndrome (NMS):** NMS, a potentially fatal symptom complex, has been reported with administration of antipsychotic drugs, including LATUDA. NMS can cause hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. The management of NMS should include: 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy; 2) intensive symptomatic treatment and medical monitoring; and 3) treatment of any concomitant serious medical problems for which specific treatments are available.

**Tardive Dyskinesia (TD):** TD is a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements that can develop in patients with antipsychotic drugs. There is no known treatment for established cases of TD, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. The risk of developing TD and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses. Given these considerations, LATUDA should be prescribed in a manner that is most likely to minimize the occurrence of TD. If signs and symptoms appear in a patient on LATUDA, drug discontinuation should be considered.

### Metabolic Changes

- **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics. Patients with risk factors for diabetes mellitus (e.g., obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.
- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

**Hyperprolactinemia:** As with other drugs that antagonize dopamine D2 receptors, LATUDA elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. In short-term, placebo-controlled studies, the increase in prolactin was greater in LATUDA-treated female patients; the median change from baseline to endpoint for females was 1.5 ng/mL and was 1.1 ng/mL in males. The increase in prolactin concentrations was dose-dependent. The proportion of female patients with prolactin elevations  $\geq 5x$  ULN was 8.3% for LATUDA-treated patients versus 1% for placebo-treated female patients. The proportion of male patients with prolactin elevations  $> 5x$  ULN was 1.9% versus 0.6% for placebo-treated male patients.

**Leukopenia, Neutropenia, and Agranulocytosis:** Leukopenia/neutropenia has been reported during treatment with antipsychotic agents. Agranulocytosis (including fatal cases) has been reported with other agents in the class. Patients with a preexisting low white blood cell count (WBC) or a history of drug induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy, and LATUDA should be discontinued at the first sign of a decline in WBC in the absence of other causative factors.

**Orthostatic Hypotension and Syncope:** LATUDA may cause orthostatic hypotension. LATUDA should be used with caution in patients with known cardiovascular disease (e.g., heart failure, history of myocardial infarction, ischemia, or conduction abnormalities), cerebrovascular disease, or conditions that predispose the patient to hypotension (e.g., dehydration, hypovolemia, and treatment with antihypertensive medications). Monitoring of orthostatic vital signs should be considered in all patients who are vulnerable to hypotension.

**Seizures:** LATUDA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold (e.g., Alzheimer's dementia).

**Potential for Cognitive and Motor Impairment:** In short-term, placebo-controlled trials, somnolence was reported in 22.3% (224/1004) of patients treated with LATUDA compared to 9.9% (45/455) of placebo patients, respectively. The frequency of somnolence increases with dose. Patients should be cautioned about operating hazardous machinery, including motor vehicles, until they are reasonably certain that therapy with LATUDA does not affect them adversely.

**Body Temperature Regulation:** Disruption of the body's ability to reduce core body temperature has been attributed to antipsychotic agents. Appropriate care is advised when prescribing LATUDA for patients who will be experiencing conditions that may contribute to an elevation in core body temperature, e.g., exercising strenuously, exposure to extreme heat, receiving concomitant medication with anticholinergic activity, or being subject to dehydration.

**Suicide:** The possibility of suicide attempt is inherent in psychotic illness and close supervision of high-risk patients should accompany drug therapy. Prescriptions for LATUDA should be written for the smallest quantity of tablets consistent with good patient management in order to reduce the risk of overdose.

**Dysphagia:** Esophageal dysmotility and aspiration have been associated with antipsychotic drug use. Aspiration pneumonia is a common cause of morbidity and mortality in elderly patients, in particular those with advanced Alzheimer's dementia. LATUDA is not indicated for the treatment of dementia-related psychosis, and should not be used in patients at risk for aspiration pneumonia.

## DRUG INTERACTIONS

**Drug Interactions:** Given the primary CNS effects of LATUDA, caution should be used when it is taken in combination with other centrally acting drugs and alcohol.

## ADVERSE REACTIONS

**Commonly Observed Adverse Reactions ( $\geq 5\%$  and at least twice that for placebo):** The most commonly observed adverse reactions in patients treated with LATUDA in short-term clinical studies were somnolence, akathisia, nausea, parkinsonism, and agitation.

Before prescribing LATUDA, please click [here](#) to read the Full Prescribing Information, including **Boxed Warning**.

If you decide you no longer wish to receive e-mail communications from Sunovion, you may opt out at any time by notifying us at 1-888-394-7377 or e-mailing [CAC@sunovion.com](mailto:CAC@sunovion.com).

# Registration Form

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**Please Print Clearly.**  
*Pre-registration required.*

By checking this box you certify that you are involved in the treatment of adult patients with schizophrenia. (*required*)

First Name                      Middle Initial                      Last Name                      Degree

Affiliation                      Medical Lic. No. or Professional Reg. No.

Specialty                      National Provider Identifier No.

E-mail Address (required for confirmation)                      Phone                      Fax

Street Address

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