Latuda® (lurasidone HCl)

Please see Important Safety Information, including **Boxed Warning**, below, and accompanying full Prescribing Information.

CONNECT WITH LEADERS IN PSYCHIATRY VIA A LATUDA PROGRAM.

Engage in a Case Through Problem-Based Learning

Woman With Depressive Symptoms and Daily Challenges With Functioning and Quality of Life

Presented by:
John Hardy, MD
Psychiatric Consultant
Division of Psychiatry
Colorado Mental Health Institute at Pueblo
Pueblo, CO

Consultant of Sunovion Pharmaceuticals Inc.

Date:
Friday, September 24, 2021

Time:
12:00 PM MT

Location:
The Pines Lodge at Beaver Creek
Executive Boardroom
141 Scott Hill Rd
Beaver Creek, CO 81620
970-429-5043

Meeting Code:
43232

Sunovion Representative:
Beth Nelson
765-635-0437
Beth.Nelson@sunovion.com

If a meal is offered, you may opt-out.

Pre-registration is required.
Sunovion is committed to partnering with venues that conform with all local and state COVID-19 public health requirements.

Register now!
Visit www.sunovionmeetings.com and enter meeting code 43232 to attend this program.

Please note: This program is subject to cancellation if fewer than 3 health care professionals are registered 3 days prior to the meeting date. This promotional, non-CME program is intended only for health care professionals involved in the treatment of patients with bipolar depression.

INDICATIONS

LATUDA is indicated for monotherapy treatment of adult and pediatric patients (10 to 17 years) with major depressive episode associated with bipolar I disorder (bipolar depression) and adjunctive treatment with lithium or valproate in adult patients with bipolar depression.

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 reevaluate the long-term usefulness of the drug for the individual patient.

The efficacy of LATUDA in the treatment of mania associated with bipolar disorder has not been established.

IMPORTANT SAFETY INFORMATION FOR LATUDA

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adults in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors.

Please see additional Important Safety Information, including **Boxed Warning**, and accompanying full Prescribing Information.

This promotional non-CME program is sponsored by sunovion

IMPORTANT SAFETY INFORMATION AND INDICATIONS FOR LATUDA

Suicidal Thoughts and Behaviors

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Contraindications:
LATUDA is contraindicated in the following:

- Known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone
- Strong CYP3A4 inhibitors (e.g., ketoconazole)
- Strong CYP3A4 inducers (e.g., rifampin)

Cerebrovascular Adverse Reactions, Including Stroke: In clinical trials, elderly patients with dementia randomized to risperidone, aripiprazole, and olanzapine had a higher incidence of stroke and transient ischemic attack, including fatal stroke. LATUDA is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS is a potentially fatal symptom complex reported with administration of antipsychotic drugs. Clinical signs of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability. Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Manage NMS with immediate discontinuation of antipsychotic drugs, including LATUDA, intensive symptomatic treatment and monitoring.

Tardive Dyskinesia (TD): The risk of developing TD (a syndrome of abnormal involuntary movements) and the potential for it to become irreversible are believed to increase as the duration of treatment and total cumulative dose of antipsychotic increase. The syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses or may even arise after discontinuation of treatment. The syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn.

Metabolic Changes: Atypical antipsychotic drugs have caused metabolic changes, including:

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 diabetes should be regularly monitored for worsening of glucose control; those with risk factors for diabetes 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 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 D_2 receptors, LATUDA elevates prolactin levels. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds.

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia/neutropenia has been reported with antipsychotics. Agranulocytosis (including fatal cases) has been reported with other agents in the class. Monitor complete blood count in patients with a pre-existing low white blood cell count (WBC)/absolute neutrophil count (ANC) or a history of drug-induced leukopenia/neutropenia. Discontinue LATUDA at the first sign of a decline in WBC in the absence of other causative factors.

Orthostatic Hypotension and Syncope: Atypical antipsychotics cause orthostatic hypotension and syncope. Generally, the risk is greatest at the beginning of treatment and when increasing dose. Monitor patients vulnerable to hypotension and those with cardiovascular and cerebrovascular disease.

Falls: Antipsychotics may cause somnolence, postural hypotension, or motor and sensory instability, which may lead to falls, causing fractures or other injuries. For patients with disease, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating treatment and recurrently during therapy.

Seizures: LATUDA should be used cautiously in patients with a history of seizures or with conditions that lower seizure threshold.

Potential for Cognitive and Motor Impairment: 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: Use LATUDA with caution in patients who may experience conditions that increase body temperature (e.g., exercising strenuously, exposure to extreme heat, concomitant medication with anticholinergic activity, or being subject to dehydration).

Dysphagia: Antipsychotics, including LATUDA, have been associated with esophageal dysmotility and aspiration, and should be used with caution in patients at risk for aspiration pneumonia.

Most Commonly Observed Adverse Reactions: The most commonly observed adverse reactions (≥5% incidence and at least twice the rate of placebo) for LATUDA:

- In adult patients: akathisia, extrapyramidal symptoms, and somnolence
- In pediatric patients (10 to 17 years): nausea, weight increase, and insomnia

To report SUSPECTED ADVERSE REACTIONS, contact Sunovion Pharmaceuticals Inc. at 877-737-7226 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

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Sunovion Pharmaceuticals Inc. is committed to the principles in the PhRMA Code on Interactions with Healthcare Professionals. This code helps to ensure that the highest professional and ethical standards are being met in the pharmaceutical industry. As part of our commitment to the PhRMA code, please note that attendance at this program is limited to health care professionals, and inclusion of spouses or other guests is not permitted.

Please see the most recent version of our privacy notice, which may change from time to time, at https://www.sunovionpolicies.com/privacy-notice.html. If you decide you no longer wish to receive communications from Sunovion, you may opt out at any time by notifying us at Sunovion Pharmaceuticals Inc., 84 Waterford Drive, Marlborough, MA 01752; at 1-888-394-7377; or at info@sunovion.com.