

Introducing LATUDA™

Shown to improve both positive and negative symptoms of schizophrenia with a proven safety profile and simple once-daily dosing¹

LATUDA™ (lurasidone HCl) is indicated for the acute treatment of patients with schizophrenia¹

Significant symptom improvement at 6 weeks demonstrated at the recommended starting dose (40 mg/day)

- PANSS* total score: statistically significant reduction observed vs. placebo (-25.7 vs. -16.0; $p < 0.001$)^{1,2†}
- CGI-S†: statistically significant reduction observed vs. placebo (-1.5 vs. -1.1; $p = 0.006$)^{1,2†}

Safety profile

- No clinically important changes for LATUDA 40 mg/day vs. placebo from baseline to endpoint (6 weeks) in total cholesterol (-0.12 vs. -0.15 mmol/L), triglycerides (-0.11 vs. -0.17 mmol/L) or glucose (0.13 vs. 0.03 mmol/L) were observed in LATUDA-treated patients¹
- In 6-week, placebo-controlled trials, mean change in weight: 0.43 kg increase for LATUDA-treated patients compared to a 0.02 kg decrease for placebo-treated patients¹
 - Proportion of patients with a $\geq 7\%$ increase in body weight at endpoint: 4.8% for LATUDA-treated patients vs. 3.3% for placebo-treated patients¹
- Discontinuation rates due to adverse events in clinical trials were 9.5% vs. 9.3% for placebo¹
- The most common side effects with incidences $\geq 5\%$ and at least twice the rate of placebo were: nausea (10% vs. 5%), somnolence (17% vs. 7%), akathisia (13% vs. 3%) and parkinsonism (10% vs. 5%)¹

Simple once-daily dosing

- Recommended starting dose: 40 mg once daily¹
- Should be administered with food (at least 350 calories independent of fat content)¹

In controlled clinical trials, LATUDA was found to improve both positive and negative symptoms. The efficacy of LATUDA was established in five short-term, 6-week controlled studies of adult patients.

The efficacy of LATUDA for long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled studies.

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).

In clinical trials, hyperglycemia or exacerbation of pre-existing diabetes has occasionally been reported during treatment with LATUDA. Patients should have baseline and periodic monitoring of blood glucose and body weight and should be monitored for symptoms of hyperglycemia.

The recommended starting dose of LATUDA is 40 mg once daily. In placebo-controlled clinical trials, once daily doses of 40, 80, 120 and 160 mg were shown to be effective. Patients should be treated with the lowest effective dose that provides optimal clinical response and tolerability, which is expected to be 40 mg or 80 mg once daily for most patients. Doses above 80 mg may be considered for certain patients based on individual clinical judgement. Dose should not exceed 40 mg/day in patients with renal or hepatic impairment.

Safety and efficacy in pediatric patients has not been evaluated and its use is not recommended.

LATUDA is not indicated in elderly patients with dementia. The safety and efficacy of LATUDA in patients 65 years of age or older has not been established.

Increased Mortality in Elderly Patients with Dementia:

Elderly patients with dementia treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Analyses of thirteen placebo-controlled trials with various atypical antipsychotics (modal duration of 10 weeks) in these patients showed a mean 1.6-fold increase in the death rate in the drug-treated patients. 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.

* Positive and Negative Syndrome Scale

† 6-week, multicenter, randomized, double-blind parallel-group study involving 478 hospitalized DSM-IV diagnosed schizophrenia patients with a PANSS total score ≥ 80 and a CGI-S score of ≥ 4 at baseline and screening. Patients were randomly assigned to receive either once-daily doses of 40 mg (n=119) or 120 mg (n=118) of LATUDA, 15 mg of olanzapine (n=122) (included to establish assay sensitivity), or placebo (n=114). Estimates and p-values for change from baseline in PANSS total score were based on a repeated measures linear regression model of the change from baseline score, with fixed effects for pooled center, visit as a categorical variable, baseline score, treatment, and treatment by visit interaction assuming an unstructured covariance matrix.^{1,2}

‡ Clinical Global Impression-Severity

References: 1. LATUDA Product Monograph. Sunovion Pharmaceuticals Canada Inc. June 18, 2012. 2. Meltzer HY, et al. Lurasidone in the treatment of schizophrenia: a randomized, double-blind, placebo- and olanzapine-controlled study. *Am J Psychiatry*. 2011 Sep;168(9):957-67. 3. Data on File (PEARL 2). Sunovion Pharmaceuticals Canada Inc.

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Inhibition of the cortex using transcranial magnetic stimulation in psychiatric populations: current and future directions

Aberrant cortical gyrification in schizophrenia: a surface-based morphometry study