

LURASIDONE HYDROCHLORIDE TABLETS



To most, “generics” means bland, ordinary, and uninteresting. To us, it means the opportunity to be remarkable.

See reverse side for important safety information.

— MAKING —
GENERICS
REMARKABLE

PRODUCT DETAILS

- Strength: Available in 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg tablets
- Therapeutic Class: Atypical Antipsychotic
- RLD: LATUDA®

NDC Numbers:

20 mg | Bottle of 30: 70436-093-04

40 mg | Bottle of 30: 70436-094-04

60 mg | Bottle of 30: 70436-095-04

80 mg | Bottle of 30: 70436-096-04

120 mg | Bottle of 30: 70436-097-04

To place an order or learn more, call **844-529-8988 (Toll Free)** or email sales@slaterunpharma.com
6am – 7pm CST (Monday - Friday)

Available through your wholesaler:

NDC: 70436-093-04
Cardinal Health: 5829098
McKesson: 2683563
Amerisource: 10277294

NDC: 70436-094-04
Cardinal Health: 5829106
McKesson: 2683571
Amerisource: 10277398

NDC: 70436-095-04
Cardinal Health: 5829114
McKesson: 2683589
Amerisource: 10277296

NDC: 70436-096-04
Cardinal Health: 5829122
McKesson: 2683597
Amerisource: 10277302

NDC: 70436-097-04
Cardinal Health: 5829130
McKesson: 2683605
Amerisource: 10277311

IMPORTANT SAFETY INFORMATION FOR: LURASIDONE HYDROCHLORIDE TABLETS

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS: AND SUICIDAL THOUGHTS AND BEHAVIORS

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Lurasidone hydrochloride is not approved for the treatment of patients with dementia-related psychosis.**
- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adult patients. Closely monitor for clinical worsening and emergence of suicidal thoughts and behaviors.**

Lurasidone Hydrochloride Tablets are contraindicated in patients:

- With known hypersensitivity to lurasidone hydrochloride or any component in the formulation. Angioedema has been observed with lurasidone.
- Taking strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.)
- Taking strong CYP3A4 inducers (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine, etc.)

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 fatality, compared to placebo-treated subjects.

A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antipsychotic drugs, including lurasidone hydrochloride. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability.

Tardive dyskinesia is a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements that can develop in patients treated with antipsychotic drugs.

Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and body weight gain.

As with other drugs that antagonize dopamine D2 receptors, lurasidone hydrochloride elevates prolactin levels.

Leukopenia/neutropenia has been reported during treatment with antipsychotic agents. Agranulocytosis (including fatal cases) has been reported with other agents in the class.

Commonly observed adverse reactions (incidence \geq 5% and at least twice the rate for placebo) were:

- Adult patients with schizophrenia: somnolence, akathisia, extrapyramidal symptoms, and nausea.
- Adolescent patients (13-17 years) with schizophrenia: somnolence, nausea, akathisia, extrapyramidal symptoms (non-akathisia), rhinitis (80mg only), and vomiting.
- Adult patients with bipolar depression: akathisia, extrapyramidal symptoms, and somnolence.

Please see the package insert for Lurasidone Hydrochloride Tablets for full prescribing information.