Latuda (lurasidone hydrochloride) - Drug Summary

Sunovion Pharmaceuticals Inc.

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Latuda
(lurasidone hydrochloride)

BOXED WARNING

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Not approved for use in patients with dementia-related psychosis. Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. Monitor closely for worsening, and for emergence of suicidal thoughts and behaviors in patients who are started on antidepressant therapy.

THERAPEUTIC CLASS

Atypical antipsychotic

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Schizophrenia

Initial: 40mg qd
Range: 40-160mg/day
Max: 160mg/day
Periodically reevaluate long-term usefulness of therapy for individual patient

Bipolar I Disorder

Treatment of major depressive episodes as monotherapy or as adjunctive therapy w/ either lithium or valproate

Initial: 20mg qd
Range: 20-120mg/day
Max: 120mg/day
Periodically reevaluate long-term usefulness of therapy for individual patient

DOSING CONSIDERATIONS

Concomitant Medications
Moderate CYP3A4 Inhibitors (eg, Diltiazem, Atazanavir, Erythromycin, Fluconazole, Verapamil):
Moderate CYP3A4 Inhibitor Added to Current Therapy w/ Lurasidone: Reduce lurasidone dose to 1/2 of the original dose level
Lurasidone Added to Current Therapy w/ a Moderate CYP3A4 Inhibitor:
Initial: 20mg/day
Max: 80mg/day

Moderate CYP3A4 Inducers:
May need to increase lurasidone dose after chronic treatment (≥7 days) w/ the CYP3A4 inducer

Renal Impairment
Moderate (CrCl 30-<50mL/min) and Severe (CrCl <30mL/min):
Initial: 20mg/day
Max: 80mg/day

Hepatic Impairment
Moderate (Child-Pugh Score 7-9):
Initial: 20mg/day
Max: 80mg/day

Severe (Child-Pugh Score 10-15):
Initial: 20mg/day
Max: 40mg/day

ADMINISTRATION

Oral route

Take w/ food (at least 350 calories)

HOW SUPPLIED

Tab: 20mg, 40mg, 60mg, 80mg, 120mg

CONTRAINDICATIONS

Known hypersensitivity to lurasidone HCl or any components in the formulation; concomitant use w/ strong CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil) or strong CYP3A4 inducers (eg, rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine).

WARNINGS/PRECAUTIONS

Neuroleptic malignant syndrome (NMS) reported; d/c immediately and institute symptomatic treatment. May cause tardive dyskinesia (TD), especially in the elderly; d/c if this occurs. May cause metabolic changes (eg, hyperglycemia, dyslipidemia, weight gain) that may increase cardiovascular (CV)/cerebrovascular risk. Hyperglycemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, reported; monitor glucose control regularly in patients with diabetes mellitus (DM) and FPG in patients at risk for DM. May elevate prolactin levels. Leukopenia, neutropenia, and agranulocytosis may occur; monitor CBC frequently during the 1st few months in patients with preexisting low WBCs or history of drug-induced leukopenia/neutropenia, and d/c at 1st sign of decline in WBCs without other causative factors. D/C therapy and follow WBCs until recovery in patients with severe neutropenia (absolute neutrophil count <1000/mm^3). May cause orthostatic hypotension and syncope; consider using a lower starting dose/slower titration and monitor orthostatic vital signs in patients at increased risk of these reactions or at increased risk of developing complications from hypotension (eg, dehydration, hypovolemia, treatment with antihypertensives, history of CV/cerebrovascular disease, antipsychotic-naive patients). Caution with history of seizures or with conditions that lower the seizure threshold. May impair mental/physical abilities. May disrupt body's ability to reduce core body temperature; caution when prescribing for patients who will be experiencing conditions that may contribute to an elevation in core body temperature (eg, concomitant anticholinergics). Closely supervise patients at high risk of suicide. May increase risk of developing a manic or hypomanic episode, particularly in patients with bipolar disorder. May cause esophageal dysmotility and aspiration; caution in patients at risk for aspiration pneumonia. Increased sensitivity reported in patients with Parkinson's disease or dementia with Lewy bodies. Evaluate for history of drug abuse; observe for drug misuse/abuse in these patients.

ADVERSE REACTIONS

Somnolence, akathisia, N/V, extrapyramidal symptoms, agitation, dyspepsia, back pain, dizziness, insomnia, anxiety, restlessness, diarrhea, dry mouth, nasopharyngitis.

DRUG INTERACTIONS

See Contraindications. Grapefruit/grapefruit juice may inhibit CYP3A4 and alter concentrations; avoid concomitant use. Adjust lurasidone dose when used in combination with moderate CYP3A4 inhibitors/inducers.

PREGNANCY AND LACTATION

Category B, not for use in nursing.

MECHANISM OF ACTION

Benzisothiazol derivative; not established. Efficacy could be mediated through a combination of central dopamine type 2 and serotonin type 2 receptor antagonism.

PHARMACOKINETICS

Absorption: T_{max}=1-3 hrs. **Distribution:** (40mg) V_d=6173L; plasma protein binding (~99%). **Metabolism:** Mainly via CYP3A4; oxidative N-dealkylation, hydroxylation of norbornane ring, and S-oxidation; ID-14283 and ID-14326 (active metabolites), ID-20219 and ID-20220 (major metabolites). **Elimination:** Urine (9%), feces (80%); (40mg) $T_{1/2}$=18 hrs.

ASSESSMENT

Assess for dementia-related psychosis, DM, renal/hepatic impairment, drug hypersensitivity, any other conditions where treatment is cautioned, pregnancy/nursing status, and possible drug interactions. Obtain baseline FPG in patients with DM or at risk for DM. Obtain baseline CBC if at risk for leukopenia/neutropenia.

MONITORING

Monitor for signs/symptoms of clinical worsening, suicidality, unusual changes in behavior, NMS, TD, hyperglycemia, hyperprolactinemia, orthostatic hypotension/syncope, cognitive/motor impairment, seizures, disruption of body temperature, manic/hypomanic episodes, esophageal dysmotility, aspiration, and other adverse reactions. Monitor FPG in patients with DM or at risk for DM, lipid profile, and weight. Monitor CBC frequently during the 1st few months in patients with preexisting low WBCs or history of drug-induced leukopenia/neutropenia. Monitor for fever or other signs/symptoms of infection in patients with neutropenia. Periodically reevaluate long-term usefulness for individual patient.

PATIENT COUNSELING

Advise to monitor for the emergence of suicidal thoughts and behavior, manic/hypomanic symptoms, irritability,

agitation, or unusual changes in behavior and to report such symptoms to physician. Counsel about signs/symptoms of NMS (eg, hyperpyrexia, muscle rigidity, altered mental status, autonomic instability), hyperglycemia, and DM. Advise of the risk of dyslipidemia, weight gain, CV reactions, and orthostatic hypotension. Advise patients with preexisting low WBCs or history of drug-induced leukopenia/neutropenia to have their CBC monitored. Instruct to use caution when performing activities requiring mental alertness (eg, operating hazardous machinery, driving) until patients are reasonably certain that therapy does not affect them adversely. Instruct to notify physician if pregnant/intending to become pregnant, or if taking/planning to take any other medications. Advise to avoid alcohol while on treatment. Counsel regarding appropriate care in avoiding overheating and dehydration.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F).

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