LURASEREN® 40mg 80mg

Lurasidone HCl

لُوراسیرین

(لُوراسیڈون ہائیڈروکلورائیڈ)

۴۰ ملی گرام ۸۰ ملی گرام

Luraseren 40mg Tablets
Each film coated tablet contains:
Lurasidone Hydrochloride (Mfg. Specs) 40mg
Product complies as per Innovator's Specifications.

Luraseren 80mg Tablets
Each film coated tablet contains:
Lurasidone Hydrochloride (Mfg. Specs) 80mg
Product complies as per Innovator's Specifications.

INDICATIONS AND CLINICAL USE

Adults :

1. Schizophrenia : LURASEREN (lurasidone HCl) is indicated for the management of the manifestations of schizophrenia.

2. Depressive Episodes Associated with Bipolar I Disorder LURASEREN is indicated as monotherapy or as adjunctive therapy with lithium or valproate for the acute management of depressive episodes associated with bipolar I disorder.

Geriatrics (>65 years of age):
LURASEREN is not indicated in elderly patients with dementia. The safety and efficacy of LURASEREN in patients 65 years of age or older has not been established.

Pediatrics (<18 years of age):
When prescribing to adolescents with schizophrenia or adolescents with depressive episodes associated with bipolar I disorder, clinicians must take into account the safety concerns associated with all antipsychotic drugs which include: extrapyramidal effects, hyperglycemia, weight gain, and hyperlipidemia, which can be more frequent or more severe in this patient population than in adults. LURASEREN should only be prescribed to adolescents with schizophrenia or bipolar I disorder by clinicians who are experienced in the diagnosis and treatment of adolescents with psychiatric illness and who are experienced in the early detection and management of the above-mentioned safety issues associated with this class of drugs.

Schizophrenia: LURASEREN is indicated for the management of the manifestations of schizophrenia in adolescents (15-17 years).

Depressive Episodes Associated with Bipolar I Disorder: LURASEREN is indicated as monotherapy for the acute management of depressive episodes associated with bipolar I disorder in adolescent (13 to 17 years) patients.

DOSAGE AND ADMINISTRATION
LURASEREN should be taken with food (at least 350 calories). Administration with food substantially increases the absorption of LURASEREN .

INDICATION	STARTING DOSE	RECOMMENDED DOSE
Schizophrenia	40 mg per day	40 to 160mg per day
Schizophrenia (adolescent 13-17 years)	40 mg per day	40 to 80mg per day
Bipolar depression	20 mg per day	20 to 120 mg per day

Moderate and Severe Renal Impairment:
Recommended starting dose is 20 mg per day, and the maximum recommended dose is 80 mg per day.

Moderate and Severe Hepatic Impairment:
Recommended starting dose is 20 mg per day. The maximum recommended dose is 80 mg per day in moderate hepatic impairment and 40 mg per day in severe hepatic impairment.

Concomitant Use of a Moderate CYP3A4 inhibitor (e.g., diltiazem):
LURASEREN dose should be reduced to half of the original dose level. Recommended starting dose is 20 mg per day. Maximum recommended dose is 80 mg per day.

Concomitant Use of a Moderate CYP3A4 Inducer:
It may be necessary to increase the dose of LURASEREN .

CONTRAINDICATIONS:
LURASEREN (lurasidone HCl) is contraindicated in any patient with a known hypersensitivity to lurasidone HCl or any components in the formulation.

Special Populations
Pregnant Women Teratogenic Effects: There are no adequate and well-controlled studies of LURASEREN in pregnant woman. Lurasidone was not teratogenic in rats and rabbits.

Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with LURASEREN . LURASEREN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labour and Delivery The effect of LURASEREN on labour and delivery in humans is unknown. Nursing Women LURASEREN was excreted in milk of rats during lactation. It is not known whether LURASEREN or its metabolites are excreted in human milk. It is recommended that women receiving LURASEREN should not breast-feed.

Pediatrics (<18 Years of age)
When prescribing to adolescents with schizophrenia (15-17 years of age) or adolescents with depressive episodes associated with bipolar I disorder (13 -17 years of age), clinicians must take into account the safety concerns associated with all antipsychotic drugs.

Use in Patients with Hepatic Impairment:
Caution should be exercised when starting LURASEREN in patients with hepatic impairment. The recommended starting dose is 20 mg. Patients should be treated with the lowest effective dose that provides optimal clinical response and tolerability, which is expected to be 20-40 mg once daily for most patients with moderate or severe hepatic impairment (Child Pugh Class B and C). The dose should not exceed 40 mg/day in patients with severe hepatic impairment, and 80 mg/day in patients with moderate hepatic impairment patients with moderate hepatic impairment.

CLINICAL PHARMACOLOGY
Mechanism of Action:
The mechanism of action of lurasidone in the treatment of schizophrenia and bipolar depression is unknown. However, its efficacy in schizophrenia and bipolar depression could be mediated through a combination of central dopamine D2 and serotonin Type 2 (5HT2A) receptor antagonism.

Pharmacodynamics:
Lurasidone is an antagonist with high affinity binding at the dopamine D2 receptors (Ki of 1 nM) and the serotonin 5-HT2A (Ki of 0.5 nM) and 5-HT7 (Ki of 0.5 nM) receptors. It also binds with moderate affinity to the human α2C adrenergic receptors (Ki of 11 nM), is a partial agonist at 44 Reference ID: 4046300 serotonin 5-HT1A (Ki of 6.4 nM) receptors, and is an antagonist at the α2A adrenergic receptors (Ki of 41 nM). Lurasidone exhibits little or no affinity for histamine H1 and muscarinic M1 receptors (IC50 > 1,000 nM).

Pharmacokinetics:
The activity of LURASEREN is primarily due to the parent drug.
The pharmacokinetics of LURASEREN is dose-proportional within a total daily dose range of 20 mg to 160 mg. Steady-state concentrations of LAURASEREN are reached within 7-days of starting LURASEREN .
Following administration of 40 mg of LURASEREN , the mean elimination half-life was 7-hours.

Absorption and Distribution:
LURASEREN is absorbed and reaches peak serum concentrations in approximately 1-3 hours. It is estimated that 9-19% of an administered dose is absorbed.
Following administration of 40 mg of LURASEREN , the mean (%CV) apparent volume of distribution was 6173 (17.2) L. LURASEREN is highly bound (~99%) to serum proteins.

Metabolism and Elimination:
LURASEREN is metabolized mainly via CYP3A4
Total excretion of radioactivity in urine and feces combined was approximately 89%, with about 80% recovered in feces and 9% recovered in urine, after a single dose of [14C]-labeled LURASEREN .

Following administration of 40 mg of LAURASEREN, the mean (%CV) apparent clearance was 3902 (18.0) mL/min.

ADVERSE REACTIONS:
Commonly observed adverse reactions (incidence ≥ 5% and at least twice the rate for placebo) were
• Schizophrenia: somnolence, akathisia, extrapyramidal symptoms, and nausea
• Bipolar depression : akathisia, extrapyramidal symptoms, and somnolence

DOSAGE FORMS AND STRENGTHS:
Tablets: 40 mg & 80 mg (SCORED TABS)
Packsize:
40 mg 10's, 20's and 30's.
80 mg 10's, 20's and 30's.

STORAGE CONDITIONS AND OTHER INFORMATION
• Keep this medicine out of the sight and reach of children.
• Do not use this medicine after the expiry date which is stated on the carton and on the blister after EXP.
• Do not throw away any medicines via wastewater or household waste.

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS AND SUICIDAL THOUGHTS AND BEHAVIORS
• Elderly patient with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. LURASEREN is not approved for the treatment of patients with dementia related psychosis.
• Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and your adult patients. chlosely monitor for clinical worsening and emergence of suicidal thoughts and behaviors. LURASEREN is not approved for use in pediatric patients with depression.

ہدایات:
- خوراک ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
- دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر روشنی سے بچا کر خشک جگہ پر رکھیں۔
- صرف رجسٹرڈ ڈاکٹر کے نسخے پر ہی فروخت کریں۔
- بچوں کی پہنچ سے دور رکھیں۔

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