

Escitalopram

Lexdin

10 mg • 20 mg
Film-Coated Tablet
ANTIDEPRESSANT

WARNING: Selective Serotonin Reuptake Inhibitors (SSRIs) are associated with increased risk of suicidal thinking and behavior in children, adolescents, and young adults (<24 years) taking antidepressants for major depressive disorders and other psychiatric illnesses.

Formulation:

Each film-coated tablet contains:

Escitalopram (as oxalate), USP.....10 mg
Escitalopram (as oxalate), USP.....20 mg

Product Description:

Escitalopram Film-Coated Tablet (Lexdin) is an orally administered Selective Serotonin Reuptake Inhibitor (SSRI).

Escitalopram 10 mg (Lexdin) is a white, oval-shaped film-coated tablet, scored on one side and plain on the other side.

Escitalopram 20 mg (Lexdin) is a yellow, oval-shaped film-coated tablet, scored on one side and plain on the other side.

Pharmacokinetics:

Escitalopram is readily absorbed from the gastrointestinal tract and maximum plasma concentrations are reached 2 to 4 hours after oral administration. It is widely distributed throughout the body (protein binding <80%). It is metabolized by demethylation, deamination, and oxidation to its active metabolites. Its elimination half-life is reported to be about 33 hours. It is excreted mainly via the liver (85%) with the remainder via the kidneys. About 12% of the daily dose is excreted in the urine as an unchanged drug. It is distributed into breast milk in low concentrations.

Pharmacodynamics:

Escitalopram is a highly Selective Serotonin Reuptake Inhibitor (SSRI) with minimal effects on norepinephrine and dopamine neuronal reuptake. Escitalopram has no or very low affinity for serotonergic or other receptors including alpha-adrenergic and beta-adrenergic, dopamine, histamine, muscarinic, and benzodiazepine receptors. Escitalopram also does not bind to, or has low affinity for, various ion channels including Na⁺, K⁺, Cl⁻, and Ca⁺⁺ channels. Antagonism of muscarinic, histaminergic, and adrenergic receptors has been hypothesized to be associated with various anticholinergic, sedative, and cardiovascular side effects of other psychotropic drugs.

Indications:

Escitalopram Film-Coated Tablet (Lexdin) is an antidepressant under the class of Selective Serotonin Reuptake Inhibitor (SSRI) for the treatment of Major Depressive Disorder (MDD) and Generalized Anxiety Disorder (GAD), Social Anxiety Disorder (SAD), or Panic Disorder in adults.

Dosage and Administration:

Escitalopram Film-Coated Tablet (Lexdin) is given by mouth usually as a single daily dose.

In treatment of depression: The initial dose is 20 mg daily by mouth. After at least one week, the dose may be increased to 40 mg once daily. A dose of 60 mg daily may be necessary for some patients.

In the treatment of panic disorder with or without agoraphobia: the initial dose is 10 mg daily by mouth increasing to 20 mg daily after one week. The dose may be increased thereafter as required up to a maximum of 60 mg daily.

In treatment of Generalized-Anxiety Disorder (GAD), Social Anxiety Disorder (SAD) and Obsessive Compulsive Disorder (OCD): Similar to those used in depression.

Initial treatment with half the usual recommended dose and a lower maximum dose should be considered in elderly patients.

Or as prescribed by the physician.

Undesirable Effects:

Effects on the blood: Abnormalities in platelet aggregation

Effects on the cardiovascular system: Orthostatic hypotension and decreased heart rate with ECG changes

Effects on endocrine system: Syndrome of inappropriate antidiuretic hormone secretion (SIADH) with hyponatremia; Hyperprolactenemia; Galactorrhea

Effects on the eyes: Symptoms of glaucoma, anisocoria (uneven pupillary dilation), mydriasis

Effects on the gastrointestinal tract: Upper gastrointestinal bleeding, gastrointestinal disturbance such as nausea, vomiting, stomach pain, dyspepsia, constipation and diarrhea

Effects on skin: Toxic epidermal necrolysis; Atypical lymphoid hyperplasia; Excessive sweating, pruritus, skin rashes and urticaria

Epileptogenic effects: Seizures and convulsions

Extrapyramidal effects: Tics, orofacial dystonias, dyskinesias and akathisia have been reported

Neurological side effects: Anxiety, restlessness, nervousness and insomnia, drowsiness and fatigue, headache, tremor, dizziness, convulsions and hallucinations

Hypersensitivity Reactions: Angioedema and anaphylaxis

**"For suspected adverse drug reaction, report to FDA: www.fda.gov/ph.
Seek medical attention immediately at first sign of any adverse drug reaction."**

Warnings and Precautions:

Escitalopram Film-Coated Tablet (Lexdin) may cause drowsiness or dizziness. The effect may be worse when taken with alcohol. Use this product with caution. Do not drive or perform any other possibly unsafe task when taking this product.

One to four weeks may pass before symptoms improve. Do not take more than the recommended dose, change your dose, or use Escitalopram Film-Coated Tablet (Lexdin) for longer than prescribed without consulting your doctor.

Contraindications:

Hypersensitivity: It is contraindicated in patients with hypersensitivity to escitalopram or any of the inactive ingredients in Escitalopram Film-Coated Tablet (Lexdin).

Monoamine Oxidase Inhibitors: The use of MAOIs intended to treat psychiatric disorders with this medication is contraindicated because of an increased risk of serotonin syndrome. The use of Escitalopram Film-Coated Tablet (Lexdin) within 14 days of stopping a MAOI intended to treat psychiatric disorders is also contraindicated. Starting Escitalopram Film-Coated Tablet (Lexdin) administration in a patient who is being treated with MAOIs is also contraindicated.

Pregnancy and Lactation:

Pregnancy category C: Either studies in animals have revealed adverse effects on the fetus and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Drug causes potential risk of persistent pulmonary hypertension of the newborn when used during pregnancy. The drug is excreted in breast milk.

Drug Interactions:

Antidepressants: Severe adverse reactions including serotonin syndrome (e.g. agitation, ataxia, diaphoresis, diarrhea, fever, hyperreflexia, myoclonus, shivering, and changes in mental status) may occur in patients receiving SSRIs in combination with Monoamine Oxidase Inhibitors (MAOIs).

Anticoagulants: This drug may cause an increase in the anticoagulant activity of Warfarin.

Antiepileptics: This drug may increase plasma concentration of Carbamazepine and Phenytoin.

Antihistamines: This drug may increase plasma concentration of Astemizole, Terfenadine by inhibition of their hepatic metabolism, increasing the risk of ventricular arrhythmias.

Antiviral: Plasma concentration of Escitalopram may be increased by HIV-protease inhibitors.

Gastrointestinal Drug: It may cause acute dystonia to some patients after coadministration with Metoclopramide.

Hypnotics: There is a risk for visual hallucinations in patients concomitantly taking Zolpidem with this drug.

Overdosage and Management:

Symptoms of overdose may include convulsion, coma, dizziness, hypotension, insomnia, nausea, vomiting, sinus tachycardia, somnolence, and ECG changes (including QT prolongation and very rare cases of torsades de pointes) and rarely, acute renal failure.

Establish and maintain an airway to ensure adequate ventilation and oxygenation. Gastric evacuation by lavage and use of activated charcoal should be considered. Careful observation and cardiac and vital sign monitoring are recommended, along with general symptomatic and supportive care. Due to the large volume of distribution of escitalopram, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit.

There are no specific antidotes for this drug. In managing overdosage, consider the possibility of multiple-drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of any overdose.

CAUTION:

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

Keep out of reach of children.

AVAILABILITY:**Escitalopram 10 mg**

Film-Coated Tablet (Lexdin)..... In Alu-PVC Clear Blister x 10's (Box x 30's)

Registration No.: DRP-7781

Date of First Authorization: March 2016

Escitalopram 20 mg

Film-Coated Tablet (Lexdin)..... In Alu-PVC Clear Blister x 10's (Box x 30's)

Registration No.: DRP-7782

Date of First Authorization: March 2016

Date of Revision of Package Insert: March 2017

Manufactured for:

MEDCHOICE CNS PHARMA CORPORATION

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By:

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