

Losita[®]

Escitalopram film coated tablet

DESCRIPTION

Losita[®] is a super selective serotonin (5-HT) reuptake inhibitor with potent antidepressant and anxiolytic activity. Its extreme selectivity appears to be unique amongst the selective serotonin reuptake inhibitors (SSRIs).

INDICATIONS

Losita[®] is indicated for:

Treatment of major depressive disorder, generalized anxiety disorder, panic disorder with or without agoraphobia, social anxiety disorders.

DOSAGE AND ADMINISTRATION

Losita[®] is administered as a single daily dose and may be taken with or without food.

Major depressive disorder:

Usual dosage is 10 mg once daily. Depending on individual patient response, the dose may be increased to a maximum of 20 mg daily. Usually 2-4 weeks are necessary to obtain antidepressant response. After the symptoms resolve, treatment for at least 6 months is required for consolidation of the response.

Generalized anxiety disorder:

Initial dosage is 10 mg once daily. Depending on the individual patient's response, the dose may be increased to a maximum of 20 mg daily. Long-term treatment for the responders can be continued for at least 6 months on 20 mg daily.

Panic disorder with or without agoraphobia:

An initial dose of 5 mg is recommended for the first week before increasing the dose to 10 mg daily. The dose may be further increased, up to a maximum of 20 mg daily, dependent on individual patient response.

Maximum effectiveness is reached after about 3 months. The treatment lasts several months.

Social anxiety disorder:

Usual dosage is 10 mg once daily. Usually 2-4 weeks are necessary to obtain symptom relief. The dose may subsequently, depending on individual patient response, be decreased to 5 mg or increased to a maximum of 20 mg daily.

Use in children and adolescents under 18 years of age:

Not recommended.

CONTRAINDICATION

Hypersensitivity to active ingredient of the formulation.

SIDE-EFFECTS

Side-effects are most frequent during the first or second week of treatment and usually decrease in intensity and frequency with continued treatment. Most common side effects are- decreased appetite, decreased libido, insomnia, somnolence, dizziness, sinusitis, nausea, diarrhoea, constipation, sweating increased, ejaculation disorder, impotence, fatigue, pyrexia.

OVERDOSE

Symptoms of overdose includes tremor, somnolence, unconsciousness, seizures, tachycardia, changes in the ECG, respiratory depression etc. There is no specific antidote. Establish and maintain an airway, ensure adequate oxygenation and respiratory function. Gastric lavage should be carried out as soon as possible after oral ingestion. The use of activated charcoal should be considered. Cardiac and vital signs monitoring are recommended along with general symptomatic supportive measures.

DRUG INTERACTIONS

CNS drugs - Caution should be used when Escitalopram is taken in combination with other centrally acting drugs.

MAO Inhibitors - There have been reports of serious, sometimes fatal reactions when Escitalopram is taken in combination with MAO inhibitors.

PRECAUTIONS

There have been spontaneous reports of adverse events occurring upon discontinuation of this drug (dysphoric mood, irritability, agitation, anxiety, confusion, sensory disturbances, insomnia, dizziness etc), particularly when abrupt. A gradual reduction in the dose rather than abrupt cessation is recommended to avoid possible withdrawal reactions.

USE IN PREGNANCY AND LACTATION

Use in pregnancy:

There are limited clinical data available regarding its use in pregnancy. The risk for humans is unknown. Therefore, Escitalopram should not be used during pregnancy unless clearly necessary and only after careful consideration of the risk/benefit.

Use in lactation:

It is expected that Escitalopram will be excreted into human milk. Breast-feeding women should not be treated with Escitalopram or breast-feeding should be discontinued.

PHARMACEUTICAL PRECAUTION

Store below 30 °C temperature, away from light & wet place. Keep out of reach of children.

PACKAGING

Losita[®] 5 tablet : Box containing 4 strips of 10 tablets each. Each film coated tablet contains Escitalopram Oxalate USP equivalent to Escitalopram 5 mg.

Losita[®] 10 tablet : Box containing 2 strips of 10 tablets each. Each film coated tablet contains Escitalopram Oxalate USP equivalent to Escitalopram 10 mg.

Losita[®] 20 tablet : Box containing 2 strips of 10 tablets each. Each film coated tablet contains Escitalopram Oxalate USP equivalent to Escitalopram 20 mg.

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Manufactured by
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