## Recita Escitalopram Oxalate USF

## Composition:

Recita 5 mg Tablet: Each film coated tablet contains Escitalopram Oxalate USP equivalent to Escitalopram USP 5 mg.

Recita 10 mg Tablet: Each film coated tablet contains Escitalopram Oxalate USP equivalent to Escitalopram USP 10 mg.

Pharmacology: Escitalopram is an oral drug that is used for treating depression and generalized anxiety disorder. It works by affecting neurotransmitters in the brain, the chemical messengers that nerves use to communicate with one another. Neurotransmitters are made and released by nerves and then travel to other nearby nerves where they attach to receptors on the nerves. Some neurotransmitters that are released do not bind to receptors and are taken up by the nerves that produced them. This is referred to as "reuptake." Many experts believe that an imbalance of neurotransmitters is the cause of depression. Escitalopram prevents the reuptake of one neurotransmitter, serotonin by nerves and an action which results in more serotonin in the brain to attach to receptors.

Indications: Escitalopram is approved for the treatment of following disorders:

- Major Depressive Disorder.
  - Panic disorder with or without agoraphobia.
  - Social phobia.
- Generalized anxiety disorder.
- Obsessive-Compulsive disorder

**Dosage and administration:** Recita (Escitalopram) is administered as a single daily dose and may be taken with or without food. Major depressive episodes: Usual dosage is 10 mg once daily. Depending on individual patient response, the dose may be increased to a maximum of 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. Usually 2-4 weeks are necessary to obtain symptom relief. The dose may subsequently, depending on individual patient response. 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. Treatment for 12 weeks is recommended to consolidate response. Generalized anxiety disorder: Initial dosage is 10 mg once daily. Depending on the individual patient response, the dose may be increased to a maximum of 20 mg daily. Obsessive-compulsive disorder: Initial dosage is 10 mg once daily. Depending on the individual patient response, the dose may be increased to a maximum of 20 mg daily. Elderly patients (> 65 years of age): Initial dosage is 5 mg once daily. Depending on individual patient response the dose may be increased to 10 mg daily. Paediatric population: Recita (Escitalopram) should not be used in the treatment of children and adolescents under the age of 18 years.

**Contraindication:** Concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) is contraindicated. Concomitant use in patients taking pimozide is contraindicated. Recita is contraindicated in patients with known hypersensitivity to Escitalopram or citalopram or any of the inactive ingredients.

Warnings and Precautions: Depression is associated with an increased risk of suicidal thoughts, self-harm and suicide (suicide-related events). Patients with a history of suicide-related events or those exhibiting a significant degree of suicidal ideation prior to commencement of treatment are known to be at greater risk of suicidal thoughts or suicide attempts and should receive careful monitoring during treatment. Close supervision of patients and in particular those at high risk should accompany drug therapy especially in early treatment and following dose changes. Discontinuation of SSRI/SNRIs (particularly when abrupt) commonly leads to discontinuation symptoms. Dizziness, sensory disturbances (including paraesthesia and electric shock sensations), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability and visual disturbances are the most commonly reported reactions. Generally these events are mild to moderate and are self-limiting; however, in some patients they may be severe or prolonged. It is therefore advised that when escitalopram treatment is no longer required, gradual discontinuation by dose tapering should be carried out.

Side Effects: The most commonly-noted side effects associated with escitalopram are agitation or restlessness, blurred vision, diarrhea, difficulty sleeping, drowsiness, dry mouth, fever, frequent urination, headache, indigestion, nausea, increased or decreased appetite, increased sweating, sexual difficulties (decreased sexual ability or desire, ejaculatory delay), taste alterations, tremor (shaking), weight changes.

Use in Pregnancy and Lactation: Escitalopram is not generally recommended for use during pregnancy, especially during first trimester. Therefore, escitalopram should not be used during pregnancy unless, in the opinion of the physician, the expected benefits to the patient outweigh the possible hazards to the fetus. Escitalopram is excreted in human milk. Consequently breast-feeding is not recommended during treatment.

Use in Children & adolescents: Recita (Escitalopram) should not be used in the treatment of children and adolescents under the age of 18 years.

Drug interactions: Escitalopram is contraindicated in combination with non-selective, irreversible MAOIs. MAO inhibitors such as moclobemide, linezolid etc should not be used with escitalopram. Caution is advised when escitalopram co-administrated with tramadol, sumatriptan and other triptans which may lead to serotonin syndrome. Patients receiving oral anticoagulant therapy should receive careful coagulation monitoring when escitalopram is started or stopped. Caution is warranted for concomitant use of hypokalaemia/hypomagnesaemia inducing medicinal products as these conditions increase the risk of malignant arrhythmias

**Overdose:** Clinical data on escitalopram overdose are limited and many cases involve concomitant overdoses of other drugs. In the majority of cases mild or no symptoms have been reported. Doses up to 800 mg of escitalopram alone have been taken without any severe symptom.

## Storage

Store in a cool (below 30°C) and dry place, protect from light. Keep all medicines out of the reach of children. How Supplied:

Recita 5 mg Tablet: Each box contains 5X10's tablets in Alu-PVC blister pack.

Recita 10 mg Tablet: Each box contains 3X10's tablets in Alu-PVC blister pack.

