

Tablets

# A-Calm

(ESCITALOPRAM)

اے-کالم  
(ایسی ٹیلوپرام) ٹیبلٹیں

**Description:**

A-Calm Tablet contain Escitalopram Oxalate which is potent selective serotonin reuptake inhibitor (SSRI). It is active isomer of citalopram.

**Composition:**

1. A-Calm 5mg Tablet: Each film coated tablet contains: Escitalopram (as oxalate) ... 5mg.
2. A-Calm 10mg Tablet: Each film coated tablet contains: Escitalopram (as oxalate) ... 10mg.
3. A-Calm 20mg Tablet: Each film coated tablet contains: Escitalopram (as oxalate) ... 20mg.

*(The product complies USP Specifications)*

**MODE OF ACTION:**

Escitalopram is a selective Serotonin (5-HT) Reuptake inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to normalize the levels of serotonin in the brain. Disturbances in the serotonin system of the brain are key factors in the development of depression and related disorders.

**PHARMACOKINETIC PROPERTIES:**

**Absorption:**

Absorption is almost complete and independent of food intake. (Mean time to maximum concentration (mean  $T_{max}$ ) is 4 hours after multiple dosing). As with racemic citalopram, the absolute bioavailability of Escitalopram is expected to be about 80%.

**Distribution:**

The apparent volume of distribution ( $V_d$ ,  $\ell$ ) after oral administration is about 12 to 26 L/kg. The plasma protein binding is below 80% for Escitalopram and its main metabolites.

**Elimination:** The elimination half-life ( $t_{1/2}$ ) after multiple dosing is about 30 hours and the oral plasma clearance ( $Cl_{oral}$ ) is about 0.6L/min. The major metabolites have a significantly longer half-life. Escitalopram and major metabolites are assumed to be eliminated by both the hepatic (metabolic) and the renal routes, with the major part of the dose excreted as metabolites in the urine.

**Indications:**

- Depressive illness.
- Generalized anxiety disorder (GAD).
- Obsessive-compulsive disorder (OCD).
- Panic disorder with or without agoraphobia.
- Fear of social situations (social phobia or social anxiety disorder).

**Contraindications:**

A-Calm is contraindicated in patients with known hypersensitivity to escitalopram oxalate, or any ingredient of the product.

**Side Effects:**

The side effects reported are agitation, restlessness, blurred vision, diarrhea, difficulty in sleeping, drowsiness, dry mouth, fever, frequent urination, headache, indigestion, nausea, increased or decreased appetite, increased sweating, sexual difficulties like decreased sexual ability or libido or ejaculatory delay, change in taste, tremor, and weight changes.

**Rarely** confusion, dizziness, lightheadedness, skin rash, itching, suicidal thoughts, and vomiting have occurred.

**Dosage and administration:**

**Adults Depression:**

The normally recommended dose of A-Calm is 10 mg taken as one daily dose. The dose may be further increased by doctor to a maximum of 20 mg per day.

**Panic disorder:**

The starting dose of A-Calm (Escitalopram) is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day.

The dose may be further increased by doctor to a maximum of 20 mg per day.

**Social anxiety disorder:**

The normally recommended dose of A-Calm (Escitalopram) is 10 mg taken as one daily dose. Doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how patient respond to the medicine.

**Generalized anxiety disorder:**

The normally recommended dose of A-Calm (Escitalopram) is 10 mg taken as one daily dose. The dose may be increased to a maximum of 20 mg per day.

**Obsessive-compulsive disorder:**

The normally recommended dose of A-calm (Escitalopram) is 10 mg taken as one daily dose. The dose may be increased to a maximum of 20 mg per day. Elderly patients (above 65 years of age). The recommended starting dose of A-Calm (Escitalopram) is 5 mg taken as one daily dose. The dose may be increased to 10 mg per day.

**In Hepatic dysfunction:**

Not more than 10 mg/day.

**In Renal dysfunction:**

No dosage adjustment required in mild to moderate renal impairment. It should be cautiously given in severe renal dysfunction.

**Overdose:**

Use of escitalopram in high doses of up to 600mg has been found to be associated with reversible symptoms like dizziness, sweating, nausea, vomiting, tremor, and somnolence. Rarely confusion, loss of consciousness, convulsions, coma, sinus tachycardia, cyanosis, hyperventilation and rhabdomyolysis might occur. In such cases following measures should be taken: airway maintenance, gastric lavage, use of activated charcoal, cardiac and vital sign monitoring and general. Symptomatic and supportive measures. There is no specific antidote for escitalopram.

**Precautions:****Use with Monoamine Oxidase Inhibitors (MAOIs):**

Like with other SSRIs, combination with monoamine oxidase inhibitor (MAOI) might result in serious, sometimes fatal, reactions including hyperthermia, rigidity, myoclonus, autonomic instability, rapid changes in vital signs, and mental status changes, including extreme agitation progressing to delirium and coma. The patients who switch from an SSRI to an MAOI might present with the same features. Hence A-Calm (Escitalopram) should not be co-administered with an MAOI or within 2 weeks of discontinuing treatment with an MAOI. Also, at least a gap of 2 weeks should be given after discontinuing A-Calm and starting an MAOI.

**Chances of Mania or Hypomania:**

Mania/hypomania might occur in patients treated with A-Calm (Escitalopram). In such cases A-Calm (Escitalopram) should be discontinued. A-Calm (Escitalopram) should be used with caution in patients with history of mania.

**Use in Patients with History of Seizures:**

Like other antidepressants, A-Calm (Escitalopram) should be cautiously used in patients with a history of seizure disorder.

**Use during Pregnancy:**

The safety of A-Calm (Escitalopram) during pregnancy has not been established. Therefore, it should not be used during pregnancy, unless the expected benefits to the patient markedly outweigh the possible hazards to the fetus.

**Use in Nursing Mothers:**

The safety of A-Calm (Escitalopram) during breast feeding has not been established. Since escitalopram is excreted in human milk, A-Calm (Escitalopram) should not be administered to nursing mothers unless the expected benefits to the patient markedly outweigh the possible hazards to the child.

**Use in Children:**

Safety and efficacy in children under the age of 18 years have not been established.

**Use in Old Age:**

Though no overall differences in safety or efficacy between old age patients and younger patients was observed, dose of 10mg is the recommend dosage for elderly patients.

**Drug Dependence:**

A-Calm (Escitalopram) is not a controlled substance. The psychological and physical dependence, and hence abuse liability, of A-Calm have been found to be low.

**Drug Interactions:**

Because of reported drug interactions, special caution should be exercised while co-administering A-Calm with monoamine oxidase Inhibitors (MAOIs), CNS drugs, alcohol, cimetidine, ketoconazole, desipramine and metoprolol.

**Storage:**

Store below 30°C.

Store in a Cool, dry place and protect from sunlight. Keep away from the reach of children.

**Presentation:**

A-Calm (Escitalopram) tablets 5mg; Pack of 14 tablets.

A-Calm (Escitalopram) tablets 10mg; Pack of 14 tablets.

A-Calm (Escitalopram) tablets 20mg; Pack of 14 tablets.

Manufactured by:



**Albert Pharmaceuticals (Pvt.) Ltd.**  
127 - Sundar Industrial Estate,  
Raiwind Road, Lahore, Pakistan.

خوراک:

ڈاکٹر کی ہدایات کے مطابق استعمال کریں۔

ہدایات:

دوا کو روشنی، نمی اور گرمی سے بچائیں۔

دوا کو ۳۰°C سے کم درجہ حرارت پر رکھیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔