

Citalam[®]

Escitalopram

Description

Citalam[®] is a preparation of Escitalopram Oxalate which is an orally administered Selective Serotonin Reuptake Inhibitor (SSRI). Escitalopram is the pure S-enantiomer of the racemic bicyclic phthalane derivative citalopram. The mechanism of antidepressant action of Citalam[®] (Escitalopram Oxalate) is presumed to be linked to potentiation of serotonergic activity in the central nervous system resulting from its inhibition of CNS neuronal reuptake of serotonin (5HT). In vitro and vivo studies in animals suggest that Escitalopram is highly Selective Serotonin Reuptake Inhibitor (SSRI) with minimal effects on norepinephrine and dopamine neuronal reuptake. Escitalopram is at least 100 folds more potent than the R-enantiomer with respect to inhibition of 5-HT reuptake and inhibition of 5-HT neuronal firing rate. Escitalopram has no or very low affinity for Serotonergic (5-HT₁₋₇) or other receptors including alpha and beta-adrenergic, Dopamine (D₁₋₅), Histamine (H₁₋₃), Muscarinic (M₁₋₅) and Benzodiazepine receptors.

Indications

Citalam[®] is indicated for the-

- Major depressive disorder
- Generalized anxiety disorder
- Obsessive-compulsive disorder
- Panic disorder
- Social anxiety disorder

Dosage and administration

Major depressive disorder, Generalized anxiety disorder & Obsessive-compulsive disorder:

Adult over 18 years: 10 mg once daily, if necessary dose can be increased to max. 20 mg daily; Elderly: initially half of adult dose, lower maintenance dose may be sufficient.

Panic disorder: Adult over 18 years: initially 5 mg once daily, dose can be increased to 10 mg daily after 7 days; max. 20 mg daily; Elderly: initially half of adult dose, max. 10 mg daily.

Social anxiety disorder: Adult over 18 years: initially 10 mg once daily. Dose can be adjusted after 2-4 weeks to usual maintenance dose 5-20 mg daily. Elderly: Not recommended.

Children & adolescents (<18 years): Not recommended.

Use in special populations

Patients with hepatic and renal impairment: 10 mg/day is the recommended dose for most elderly patients and patients with hepatic impairment. No dosage adjustment is required for patients with mild or moderate renal impairment. But it should be used with caution in patients with severe renal & hepatic impairment.

Pregnancy & lactation

Pregnancy category C. No relevant epidemiological data or well controlled studies in pregnant women are available for Escitalopram. Escitalopram has had limited use in pregnancy without a reported increase in birth defects. Neonates should be observed if maternal use of Escitalopram continues into the later stages of pregnancy, particularly in the third trimester. Abrupt discontinuation should be avoided during pregnancy. This drug should be used during pregnancy only if clearly needed and only after careful consideration of the risk/benefit. It is expected that Escitalopram, like citalopram, will be excreted into human breast milk.

Side effects

Common side effects include constipation, decreased interest in sexual intercourse, diarrhea, dry mouth, gas in the stomach, heartburn, Sexual dysfunction (ejaculation delay, inability to have or keep an erection, loss in sexual ability, desire, drive or performance), sleepiness or unusual drowsiness, trouble sleeping.

Less common side effects are bloated or full feeling, burning, crawling, itching, numbness, tingling feelings, chills, cough, decreased appetite, excess air or gas in the stomach, fever, increased sweating, joint pain, muscle aches and pains, pain in the neck or shoulders, passing gas, runny nose, sneezing, sore throat, stuffy nose, tightness of the chest, tooth problems, trouble breathing, unusual dreams, drowsiness & tiredness.

Precautions

Escitalopram should be used with caution in patients with epilepsy (avoid if poorly controlled, discontinue if convulsions develop), cardiac disease, diabetes mellitus, susceptibility to angle-closure glaucoma, a history of mania or bleeding disorders (especially gastro-intestinal bleeding) and if used with other drugs that increase the risk of bleeding, hepatic impairment & renal impairment. It should also be used with caution in those receiving concurrent electroconvulsive therapy. Escitalopram may also impair performance of skilled tasks (e.g. driving).

Drug interaction

Escitalopram should not be started until 2 weeks after stopping an MAOI. Conversely, an MAOI should not be started until at least a week after Escitalopram or related antidepressant has been stopped.

Overdose

Symptoms most often accompanying Escitalopram overdose, alone or in combination with other drugs or alcohol include convulsions, coma, dizziness, hypotension, insomnia, nausea, vomiting, sinus tachycardia, somnolence and ECG changes (including QT prolongation).

There are no specific antidotes for Escitalopram. 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 & 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.

Contraindications

Escitalopram should not be used if the patient enters a manic phase, hypersensitive to Escitalopram and any excipients of the product, the patient is taking monoamine oxidase inhibitor (MAOI), reversible MAOI (RIMA) and moclobemide.

Pharmaceutical precautions

Store in a cool & dry place. Protect from light. Keep out of the reach of children.

Presentation

Citalam[®] 5 tablet : Each coated tablet contains Escitalopram 5 mg as Oxalate USP.

Citalam[®] 10 tablet: Each coated tablet contains Escitalopram 10 mg as Oxalate USP.

Package quantities

Citalam[®] 5 tablet : Carton of 30 tablets in blister pack.

Citalam[®] 10 tablet: Carton of 30 tablets in blister pack.

® Registered Trade Mark



ACI Limited

Narayanganj, Bangladesh