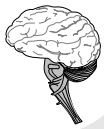

Oxapro®

Escitalopram

Antidepressant

COMPOSITION

Oxapro® Tablet : Each film-coated tablet contains Escitalopram 10 mg (as Escitalopram Oxalate INN).

PHARMACOLOGY

Oxapro® (Escitalopram Oxalate) is an orally administered Selective Serotonin Reuptake Inhibitor (SSRI). Escitalopram is the pure S-enantiomer of the recemic bicyclic phthalane derivative citalopram.

The mechanism of antidepressant action of Oxapro® (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 fold more potent than the R-enantiomar 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.

INDICATION

Escitalopram Oxalate is indicated for the treatment of major depressive disorder and maintenance therapy to prevent people with depression from suffering a relapse. A major depressive episode implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor retardation or agitation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, a suicide attempt or suicidal ideation.

DOSAGE AND ADMINISTRATION

Adults : The initial dose of Oxapro® (Escitalopram Oxalate) is 10 mg once daily. (A fixed dose trial of Escitalopram Oxalate demonstrated the effectiveness of both 10 mg and 20 mg of Escitalopram Oxalate, but failed to demonstrate a greater benefit of 20 mg over 10 mg.) If the dose is increased to 20 mg, this should occur after a minimum of one week.

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Elderly : A single oral dose of 10 mg/day is the recommended dose for most elderly patients. Administered in excess recommended dose has not been yet established.

Pediatric Use : Safety and effectiveness in children below the age of 18 years have not been established.

CONTRAINDICATION AND PRECAUTION

Concomitant use in patients taking monoamine oxidase inhibitor is contraindicated. This is contraindicatd in patients with known hypersensitivity to escitalopram oxalate or citalopram.

If a patient enters a manic phase, Escitalopram Oxalate should be discontinued.

As with all drugs effective in the treatment of major depressive disorder, Escitalopram should be used cautiously in patients with a history of mania. Escitalopram Oxalate should be used with caution in patients with a history of seizure disorder.

Rarely, the occurrence of serotonin syndrome has been reported in patients receiving SSRIs.

A combination of symptoms, possibly including agitation, confusion, tremor, myoclonus and hyperthermia, may indicate the development of this condition.

The use of citalopram in hepatically impaired patients should be approved with caution and a lower maximum dosage (10 mg/day) is recommended.

Clinical experience with Escitalopram in patients with concomitant systemic illness is limited. Escitalopram should be used with caution in diabetic patients on insulin or other antidiabetic drugs.

SIDE EFFECT

The following additional adverse reactions have been reported: agitation or restlessness, blurred vision, diarrhea, 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

The safety of Escitalopram during pregnancy and lactation has not been

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established. Therefore, Escitalopram should not be used during pregnancy, unless, in the opinion of the physician, the expected benefits to the patients markedly outweigh the possible hazards to the fetus. Escitalopram is excreted in human milk. Escitalopram should not be administered to nursing mothers unless, in the opinion of the treating physician, the expected benefits to the patient markedly outweigh the possible hazards to the child.

USE IN GERIATRIC PATIENT

Escitalopram pharmocokinetics in subjects age 65 and over were compared to younger subjects in a single and multi-dose study. No overall differences in safety or effectiveness between this group and the younger subjects was observed, but greater sensitivity of some elderly individuals cannot be ruled out. 10 mg is the recommended dosage for elderly patients.

HOW SUPPLIED

Oxapro® Tablet : Each box containts 5x6 tablets in blister pack.

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