Oxapro®

Escitalopram Oxalate INN

COMPOSITION

Oxapro® 5 Tablet: Each tablet contains Escitalopram 5 mg as Escitalopram Oxalate INN.

Oxapro® 10 Tablet: Each tablet contains Escitalopram 10 mg as Escitalopram Oxalate INN.

PHARMACOLOGY

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

Escitalopram is at least 100 fold more potent than the R-enantiomar with respect to inhibition of 5-HT reuptake. Escitalopram has no or very low affinity for serotonergic or other receptors including alpha- and beta-adrenergic, Dopamine, histamine, Muscarinic and benzodiazepine receptors.

INDICATIONS

Oxapro® is indicated for acute and maintenance treatment of Major Depressive Disorder (MDD) in adults and adolescents aged 12-17 years and Generalized Anxiety Disorder (GAD) in adults.

DOSAGE & ADMINISTRATION

Adults & Adolescents (12-17 yr.): The initial recommended dose of **Oxapro®** is 10 mg once daily. If the dose is increased to 20 mg, this should occur after a minimum of one week. Elderly: 10 mg/day is the recommended dose for most elderly patients.

No dosage adjustment for patients with mild or moderate renal impairment. Use caution in patients with severe renal impairment

CONTRAINDICATION

Escitalopram is contraindicated in patients with known hypersensitivity to Escitalopram or Citalopram or any of the inactive ingredients of the drug product. Concomitant use in patients taking Monoamine Oxidase is contraindicated.

WARNINGS AND PRECAUTIONS

Clinical worsening, suicidality and unusual change in behavior should be monitored during the initial few months of therapy or at times of dose changes. Escitalopram should be prescribed with care in patients with a history of mania and seizure disorder.

ADVERSE REACTIONS

Most commonly observed adverse reactions are insomnia, ejaculation disorder (primarily ejaculatory delay), nausea, sweating increased, fatigue and somnolence, decreased libido etc.

USE IN PREGNANCY & LACTATION

Pregnancy Category: C. Use only if the potential benefit justifies the potential risk to the fetus. Escitalopram is excreted in human breast milk. So, caution should be exercised when administered to a nursing woman.

STORAGE

Protect from light and moisture, store below 30°C. Keep the medicine out of the reach of children.

HOW SUPPLIED

Oxapro® **5** Tablet: Each box contains 30 tablets in blister pack. **Oxapro**® **10** Tablet: Each box contains 30 tablets in blister pack.

Manufactured by

