ESCITALOPRAM

ZYTAPRAM

10 mg Film-Coated Tablet

ANTIDEPRESSANT

℞

FORMULATION
Each film-coated tablet contains:
Escitalopram Oxalate eq. to Escitalopram..... 10 mg

PRODUCT DESCRIPTION
White to off white, round, biconvex, plain on both side and film-coated tablet.

PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: Antidepressants, selective serotonin reuptake inhibitors.

MECHANISM OF ACTION
Pharmacology:
Escitalopram is a selective inhibitor of serotonin (5-HT) re-uptake. The inhibition of 5-HT re-uptake is the only likely mechanism of action explaining the pharmacological and clinical effects of escitalopram. Escitalopram has no or low affinity for a number of receptors including 5-HT1A, 5-HT2, DA D1 and D2 receptors, α1-, α2-, β-adrenoceptors, histamine H1, muscarine cholinergic, benzodiazepine and opioid receptors.

PHARMACOKINETICS
Absorption is independent of food intake (mean Tmax is 4 hours after multiple dosing). The apparent volume of distribution (Vd, beta/F) after oral administration is about 12 to 26 L/kg. The plasma protein binding of Escitalopram is approximately 55%. Escitalopram is metabolised in the liver to the didemethylated metabolites are partly excreted as glucoronides. Unchanged Escitalopram is the predominant compound in plasma. After multiple dosing the mean concentrations of the dimethyl and didemethyl metabolites are usually 28-31% and 5% of the Escitalopram concentration, respectively. The elimination half-life after multiple dosing is about 30 hours and the oral plasma clearance is about 0.60L/Min. Escitalopram and major metabolites are – like racemic citalopram – assumed to be eliminated by the hepatic (metabolic) and renal routes with the major part of the dose.

INDICATIONS
Used in the treatment of depression, panic disorder with or without agoraphobia, generalized anxiety disorder, social anxiety disorder, and obsessive-compulsive disorder.

DOSAGE AND ADMINISTRATION
It is given orally as the oxalate although doses are expressed in terms of the base; Escitalopram oxalate 12.8 mg is equivalent to about 10 mg of Escitalopram.
In the treatment of depression, the usual dose is 10 mg once daily increased, after at least a week, to a maximum of 20 mg once daily if necessary.
For the treatment of panic disorder with or without agoraphobia, initial doses are 5 mg once daily, increased after a week to 10 mg once daily; further increases up to a maximum of 20 mg daily may be necessary in some patients.
Initial treatment with half the usual recommended dose and a lower maximum dose should be considered in elderly patients. Patients with hepatic impairment or those who are poor metaboliser with respect to the cytochrome P450 isoenzyme CYP2C19 may also require lower doses.
Escitalopram should be withdrawn gradually to reduce the risk of withdrawal symptoms. Or as prescribed by the physician.

CONTRAINDICATIONS
Hypersensitivity to escitalopram or to any of the excipients. Children: as safety and efficacy have not been established in this population. Monoamine Oxidase Inhibitors-Cases of serious reactions have been reported in patients receiving an SSRI such as Escitalopram in combination with a monoamine oxidase inhibitor (MAOI), and in patients who have recently discontinued an SSRI and have been started on a MAOI.

PRECAUTIONS
Mania – Escitalopram should be discontinued in any patient entering a manic phase.
Paradoxial anxiety – Some patients with panic disorder may experience increased anxiety symptoms at the start of treatment with antidepressants.
Seizures – Escitalopram should be discontinued in any patient who develops seizures. It should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be closely monitored.
Diabetes mellitus – patients with diabetes mellitus, treatment with Escitalopram may alter glycaemic control, due to improvement of depressive symptoms.
Suicide – As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored during this period.
Haemorrhage – there have been reports of cutaneous bleeding abnormalities, such as ecchymoses and purpura, with Escitalopram.

Use in Pregnancy: For escitalopram, only limited clinical data are available regarding exposures in pregnancy. Escitalopram should not be used during pregnancy unless clearly necessary and only after careful consideration of the risk/benefit ratio.
In reproductive toxicity studies performed in rats with escitalopram, embryo-fetotoxic effects were observed, but no increased incidence of malformations. Using SSRIs in the 3rd trimester may result in effects, including neurobehavioral disturbances in the newborn infant.
The following effects were reported in neonates with SSRIs administered to pregnant women until date of birth: Irritability, tremor, hypertonia, increased muscle tone, constant crying, difficulty in suckling or in sleeping.
They may either indicate serotonergic effects or withdrawal syndrome. If used during pregnancy, SSRIs should never be stopped abruptly.

Use in Lactation: It is expected that escitalopram will be excreted into human milk, and breastfeeding is not recommended during treatment.

Use in Children: Use in children and adolescents (<18 years) is not recommended since efficacy has not been investigated in this population.

DRUG INTERACTIONS
Escitalopram has a low potential for clinically significant medicine interactions. In vitro studies have shown that the biotransformation of escitalopram to its demethylated metabolites depends on three parallel pathways (cytochrome P450, 2C19, 3A4 and 2D6). Escitalopram is very weak inhibitor of isoenzyme CYP1A2, 2C9, 2C19, 2E1 and 3A.
Ritonavir – The pharmacokinetics of single doses of Escitalopram was not changed by co-administration with single dose of ritonavir (CYP3A4 inhibitor).
Ketoconazole - Co-administration with ketoconazole (potent CYP3A4 inhibitor) did not change the pharmacokinetics of racemix citalopram.
MAOI, Sumatriptan and Tramadol – Co-administration with MAO inhibitors may cause serotonin syndrome.
Co-administration with other serotogenic medicines (eg. tramadol, sumatriptan) as well as other antidepressants with serotonergic properties may lead to an enhancement of serotonin associated effects, eg serotonin syndrome.

ADVERSE DRUG REACTION
Adverse reactions observed with Escitalopram are most frequently during the first one or two weeks of treatment and may decrease in intensity and frequency with continued treatment. After prolonged administration abrupt cessation of Escitalopram may produce withdrawal reactions in some patients.
Common – (> 1/100, <1/10)
Both genders:
Nausea, insomnia, somnolence, increased sweating, diarrhea, constipation, dizziness, fatigue, decreased appetite, sinusitis, decreased libido, pyrexia, yawning.
Gender specific:
Ejaculation disorder, impotence, abnormal orgasm (female).
Uncommon (>1/1000, <1/100)
Sleep disorder, taste disturbance

OVERDOSE AND TREATMENT
Toxicity: Clinical data on escitalopram overdose are limited. However, it has been observed that doses of 190 mg of escitalopram have been taken without any serious symptoms being reported.
Symptoms: Symptoms of overdose with racemic citalopram (>600 mg): Dizziness, tremor, agitation, somnolence, unconsciousness, seizures, tachycardia, changes in the ECG with ST-T changes, broadening of the QRS complex, prolonged QT interval, arrhythmias, respiratory depression, vomiting, rhabdomyolysis, metabolic acidosis, hypokalemia. It is anticipated that overdoses with escitalopram would result in similar symptoms.
Treatment: There is no specific antidote. Establish and maintain an airway, ensure adequate oxygenation and respiratory function. Gastric lavage should be carried out as soon as possible after oral ingestion. Cardiac and vital signs monitoring are recommended along with general symptomatic supportive measures.

CAUTION
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

Keep all medicines out of reach of children.

ADVERSE DRUG REACTION REPORTING STATEMENT
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION
Store at temperatures not exceeding 30°C.

AVAILABILITY
Alu/Alu Blister Pack x 10's (Box of 10's)

DRP-4826-01
Date of First Authorization: Novbember 10, 2016
Date of Revision of Package Insert: September 20, 2023

xxxxxxxx

Marketing Authorization Holder
THE CATHAY YSS DISTRIBUTORS CO., INC.
2/F Vernida I Condo., 120 Amorsolo St.,
Legaspi Vill., Makati City

Imported by
AMBICA INTERNATIONAL CORPORATION
No. 9 Amsterdam Extension, Merville Park Subd.,
Parañaque City

Manufactured for
UNOSOURCE PHARMA LTD.
503 / 504, 5th Floor, Hubtown Solaris, N.S. Phadke Marg, Andheri (East), Mumbai-400069, India

Manufactured by
AKUMS DRUGS & PHARMACEUTICALS LTD.
(Plant I-Solid Oral Dosage Facility)
Plot No. 19, 20, 21, Sector 6A-IIE, Sidcul,
Ranipur, Haridwar-249403, Uttarakhand, India