Escitalopram

Xolvpro

℞

10 mg Film Coated Tablet Antidepressant
(Selective Serotonin Reuptake inhibitor)

FORMULATION
Each tablet contains:
Escitalopram (as oxalate) 10mg

PRODUCT DESCRIPTION
White oval biconvex, film coated tablet engraved maple leaf on one side and a bisect line on the other side.

PHARMACODYNAMIC PROPERTIES
Mechanism of Action: 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 fo ra number of receptors including 5-HT1A, 5•HT2, DA, D1 and D2 receptors, α1-, α 2-, β adrenoreceptors, histamine H1, muscarine cholinergic, benzodiazepine and opioid receptors.
(For complete details on its Pharmacology please refer to the product insert.)

INDICATIONS
It is used in the treatment of depression, panic disorder with or without agoraphobia, generalized anxiety disorder and social anxiety disorder.

DOSAGE AND ADMINISTRATION
In the treatment of depression, generalized anxiety disorder and social anxiety disorder, the usual dose is 10 mg once dally increased at least after a week, to a maximum of 20 mg once daily if necessary.
Panic disorder with or without or without agoraphobia - Initial doses are 5 mg once daily, increased after a week10 10 mg once daily: further, increases up to a maximum of 20 mg dally 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 metabollsers with respect to the cytochrome P450 isoenzyme CYP2Cl9 should also receive an initial dose of 5 mg daily; the dose may be increased to 10 mg daily after 2 weeks depending on response.
Escitatopram should be withdrawn gradually to reduce the risk of withdrawal symptoms.

PRECAUTION
Because of their epileptogenic effect SSRls should be used with caution in patients with epilepsy or a history of such disorders (and should be avoided if the epilepsy is poorly controlled). Treatment should be stopped if seizures develop or when there is an increase m seizure frequency. Care is advised in patients receiving ECT as prolonged seizures have occurred rarely. SSRls should also be used with caution in patients with cardiac diseases or a history of bleeding disorders. Although SSRls are preferred to tricyclics for the treatment of depression in patients with diabetes, they may alter glycaemic control and therefore caution is also warranted in diabetics subjects. SSRls should also be used with caution in patients with angle-closure & glaucoma.

USE IN PREGNANCY AND LACTATION
Use In Pregnancy: For escitalopram, only limited clinical data are available regarding exposure iIn pregnancy. Escitalopram should not be used during pregnancy unless clearly necessary and only after careful consideration of the risk/benefit ratio.

If used during pregnancy, SSRIs should never be stopped abruptly due to potential serotonergic effect or withdrawal syndrome.
Use in lactation: It is expected that escitalopram will be excreted into human milk, and breastfeeding is not recommended during treatrnent.

ADVERSE DRUG REACTION

Adverse reactions are more frequent during the1s tor 2nd week of treatment and usually decrease in intensity and frequency with continued treatment.
After prolonged administration, abrupt cessation of SSRIs may produce withdrawal reactions in some patients. Although withdrawal reactions may occur on stopping the therapy, the available preclinical and clinical evidence does not suggest that SSRIs cause dependence. Withdrawal symptoms (dizziness, headache and nausea) have been observed in some patients after abrupt discontinuation of escitalopram treatment. Most symptoms were mild and self-limiting. In order to avoid withdrawal reactions, tapered discontinuation over 1·2 weeks recommended.
(For complete details on Adverse Drug Reactions please refer to the product insert.)

DRUG INTERACTIONS

SSRIs interact with other drugs mainly as a result of their inhibitory activity on hepatic cytochrome P450 isoenzymes. Individual SSRIs do not all exhibit the same degree of inhibition nor do they react with the isoenzymes. The drugs inhibited by specific SSRIs depends on the isoenzymes affected.
As SSRIs have occasionally been associated with bleeding disorders and other effects on the blood, caution is advised when they are given with drugs known to affect platelet function.
Although different antidepressants have been used together under expert supervision in refractory cases of depression, severe adverse reactions including the serotonin syndrome may occur.

OVERDOSE ANDTREATMENT

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 of overdose with racemic citalopram (>600 mg): Dizziness, trernor, agitation, somnolence, unconsciousness, seizures, tachycardia, changes in the ECG with ST-T changes. broadening ol 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 and vital signs monitoring are recommended along with general symptomatic supportive measures.

CAUTION

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.
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 temperature snot exceeding 30'C. Keep all medicines out of reach of children.

AVAILABILITY

Alu/Alu PVC Blister Pack x 7's (Box of 14’s)

DRP-4162

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(For complete Product information please refer to the product insert.)