Olanzapine

Xolvprex

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

FORMULATION
Each tablet contains:
Olanzapine 10mg

PRODUCT DESCRIPTION
Orange colored round shape biconvex, film coated tablet plain on both side.

PHARMACOKINETICS
Olanzapine is well absorbed from the gastrointestinal tract after oral dose but undergoes considerable first-pass metabolism. Peak plasma concentrations are achieved about 5 to 8 hours after oral dose and about 15 to 45 minutes after an intramuscular dose. Olanzapine is about 93% bound to plasma proteins. It is metabolized in the liver, by direct glucuronidation and by oxidation mediated through the cytochrome P450 isoenzymes CYP1A2, and to a lesser extent, appears to be inactive. The mean plasma elimination half-life is about 30-38 hours; Olanzapine is distributed into the breast milk.
(For complete details on its Pharmacology please refer to the product insert.)

INDICATION
For the management of schizophrenia and for the treatment of moderate to severe mania associated with bipolar disorder.

DOSAGE AND ADMINISTRATION
For the treatment of schizophrenia, the usual initial dose is 5 to 10 mg daily. Dosage adjustments beyond 10 mg daily are made at intervals of not less than 1 week; the daily dosage may be adjusted in increments or decrements of 5 mg.
For the treatment of acute mixed or manic episodes in bipolar disorder, initial dose is 10 or 15 mg daily as monotherapy or 10 mg if given as a part of combination therapy; the daily dosage may be adjusted in increments or decrements of 5 mg if necessary, at intervals of not less than 24 hours to a dose of between 5 and 20 mg daily, or as prescribed by the physician.

CONTRAINDICATION
Olanzapine is contraindicated in patients with a known hypersensitivity to the product.

WARNINGS AND PRECAUTION
During antipsychotic treatment, improvement in the patients' clinical condition may take several days to some weeks. Patients should be closely monitored during this period.
(For complete details on Warnings and Precaution please refer to the product insert.)

USE IN PREGNANCY AND LACTATION
Use In Pregnancy: Olanzapine has not been studied in pregnant women. Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with olanzapine. Olanzapine should be used in pregnancy only if the potential benefit justifies the potential risk to the future.
Use in lactation: In a study of breast-feeding healthy women, olanzapine was excreted in breast milk. Mean infant exposure (mg/kg) at steady-state was estimated to be 1.8% of the maternal olanzapine dose (mg/kg). Patients should be advised not to breastfeed an infant if they are taking

olanzapine.

SIDE EFFECTS

More common: Agitation; behavior problems; difficulty in speaking or swallowing; restlessness or need to keep moving; stiffness of arms or legs; trembling or shaking of hands and fingers. Less common: Blurred vision; chest pain; fever; flu-like symptoms; headache; inability to move eyes; itching of the vagina or genital area; lip smacking or puckering; mood or metal changes, such as anger, anxiety, giddiness, loss of memory, or nervousness; pain during sexual intercourse; pounding in the ears; puffing of cheeks; rapid or worm-like movements of tongue; rhythmic movement of muscles; slow or fast heartbeat; swelling of feet or ankles; thick, white vaginal discharge with no odor or with a mild odor; twitching movements; twitching, twisting, uncontrolled repetitive movements of tongue, lips, face, arms, or legs; uncontrolled chewing movements; uncontrolled jerking or twisting movements of hands, arms and legs; uncontrolled movements of lips, tongue, or cheeks; unusual or incomplete body or facial movements.
Rare: Changes in menstrual period; confusion; extra heartbeat; mental or physical, sluggishness; skin rash; swelling of face; trouble in breathing. Incidence not known: Bloating; cough; constipation; darkened urine; diabetic coma; difficulty swallowing; hives; indigestion; itching skin; itching, puffiness or swelling of the eyelids or around the eyes, face, lips, or tongue; large, hive-like swelling on face, eyelids, lips, tongue, throat, hands, legs, feet, sex organs; loss of appetite; nausea; pain in stomach, side, or abdomen, possibly radiating to the back; painful or prolonged erection of the penis; redness of skin; shortness of breath; skin rash; tightness in chest; unusual tiredness or weakness; vomiting, wheezing; yellow eyes or skin.
(For complete details on Adverse Drug Reactions please refer to the product insert.)

DRUG INTERACTIONS

Caution should be used when Olanzapine is taken in combination with other centrally acting drugs and alcohol. Because of its potential for inducing hypotension, Olanzapine may enhance the effects of certain antihypertensive agents. Olanzapine may antagonize the effects of levodopa and dopamine agonists. Omeprazole and rifampin, may cause an increase in Olanzapine clearance. Charcoal: The administration of activated charcoal (1 g) reduced the Cmax and AUC of Olanzapine by about 60%. Cimetidine and Antacids: single dose of cimetidine (800 mg) or aluminum and magnesium-containing antacids did not affect the oral bioavailability of Olanzapine. Carbamazepine: Carbamazepine therapy (200 mg bid) cause an approximately 50% increase in the clearance of Olanzapine. Ethanol: Ethanol (45 mg/70 kg single dose) did not have an effect on Olanzapine pharmacokinetics. Fluoxetine: Fluoxetine (60 mg single dose or 60 mg daily for 8 days) causes a small (mean 16%) increase in the maximum concentration of Olanzapine and a small (mean 16%) decrease in Olanzapine clearance. Fluvoxamine: Fluvoxamine, a CYP1A2 inhibitor, decreases the clearance of Olanzapine. This results in a mean increase in Olanzapine Cmax following fluvoxamine of 54% in female nonsmokers and 77% in male smokers. The mean increase in Olanzapine AUC is 52% and 108%, respectively. Warfarin: Warfarin (20 mg single dose) did not affect Olanzapine pharmacokinetics. Lithium: Multiple doses of Olanzapine (10 mg for 8 days) did not influence the kinetics of lithium. Valproate: Olanzapine has little potential to inhibit the major metabolic pathway, glucuronidation of valproate.
(For complete details on Drug Interactions please refer to the product insert.)

OVERDOSE ANDTREATMENT

Signs and Symptoms: Very common symptoms reported in olanzapine overdose (≥10% incidence) include tachycardia, agitation/aggressiveness, dysarthria, various extrapyramidal symptoms and reduced level of consciousness ranging from sedation to coma.
Management of Overdose: There is no specific antidote for olanzapine. Induction of emesis is not recommended. Standard procedures for management of overdose may be indicated (i.e., gastric lavage, administration of activated charcoal).
(For complete details on Overdose and Treatment please refer to the product insert.)

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 10's (Box of 30s)

DRP- 2901- 04
Date of First Authorization: September 04, ,2019
Date of Revision of Package Insert: November 15, 2022

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