MedChoice
CNS

Olanzapine

Olzadin

5 mg • 10 mg Film - Coated Tablet

ANTI-PSYCHOTIC

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

FORMULATION:
Each film-coated tablet contains:
Olanzapine .....5 mg
Olanzapine .....10 mg

PRODUCT DESCRIPTION:
Olanzapine 5 mg and 10 mg (Olzadin) are white, oval-shaped, biconvex film-coated tablets, scored on one side and plain on the other side.

INDICATIONS:
It is used in the management of schizophrenia and for short-term treatment of mania associated with bipolar disorder.

PHARMACOLOGIC ACTIONS:
Olanzapine is a thienobenzodiazepine atypical antipsychotic. It has affinity for various dopamine, serotonin and muscarinic receptors, as well as histamine (H1) and adrenergic (α1) receptors.

PHARMACOKINETICS:
Olanzapine is well absorbed from the gastrointestinal tract but undergoes considerable first-pass metabolism. Peak plasma concentrations are achieved about 5 to 8 hours after oral administration. Olanzapine is about 93% bound to plasma proteins. It is extensively metabolized in the liver primarily by direct glucuronidation and by oxidation mediated through the cytochrome P450 isoenzymes CYP1A2 and to a lesser extent CYP2D6. The two major metabolites 10-N-glucuronide and 4'-N-desmethyl olanzapine appear to be inactive. About 57% of a dose is excreted in the urine, mainly as metabolites and about 30% appears in the feces. The plasma elimination half-life has been variously reported to be about 30 to 38 hours; half-lives tend to be longer in female than in male patients.

DOSAGE AND ADMINISTRATION:
For Schizophrenia:
Initial dose: 10 mg daily as single dose by mouth; thereafter dosage adjustment of 5 mg daily may be made according to response at intervals of not less than one week to within the range of 5 mg to 20 mg daily. It is recommended that doses of 15 mg or more daily should be given only after clinical reassessment.
For patients with renal impairment: Starting dose of 5 mg daily by mouth may be necessary.
For patients with moderate hepatic insufficiency: Starting dose should be 5 mg and only increased with caution.
For Acute Manic Episodes:
Initial dose: 10 mg or 15 mg daily by mouth; dosage adjustments of 5 mg daily may subsequently be made at intervals of not less than 24 hours if necessary to within the range of 5 mg to 20 mg daily, for 3 to 4 weeks.
Or as prescribed by a physician.

CONTRAINDICATION:
Olanzapine Film-Coated Tablet (Olzadin) is contraindicated in patients with known hypersensitivity to the product.

WARNINGS AND PRECAUTIONS:
Elderly Patients with Dementia-Related Psychosis: Increased risk of death and increased incidence of cerebrovascular adverse events.
Suicide: The possibility of suicide attempt to inherent in Schizophrenia and in Bipolar I disorder, and close supervision of high-risk patients should accompany drug therapy.
Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring.
Hyperglycemia: In extreme cases, associated with ketoacidosis or hyperosmolar coma, death may occur. Patients should be monitored for symptoms of hyperglycemia and undergo fasting blood glucose testing at the beginning of, and periodically during, treatment.
Hyperlipidemia: Undesirable alterations in lipids may be observed during olanzapine treatment. Monitor patients through clinical tests such as fasting blood lipid testing at the beginning of, and periodically during, treatment.
Weight gain: Potential consequences of weight gain should be considered. Patients should receive regular monitoring of weight.
Tardive Dyskinesia: Discontinue if clinically appropriate.
Orthostatic Hypotension: Orthostatic hypotension associated with dizziness, tachycardia, bradycardia and, in some patients, syncope may occur especially during initial dose titration. Use with caution in patients with cardiovascular disease, and those conditions that could affect hemodynamic responses.
Leukopenia, Neutropenia, and Agranulocytosis: Patients with a history of clinically significant low White Blood Cell count (WBC) or drug induced leucopenia/neutropenia should have their Complete Blood Count (CBC) monitored frequently during the first few months of therapy and discontinuation should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors.
Seizures: Use cautiously in patients with a history of seizure or with conditions that potentially lower the seizure threshold.
Hyperprolactinemia: Has potential to impair judgment, thinking, and motor skills. Use with caution when operating machinery.
Potential for Cognitive and Motor Impairment: May elevate prolactin levels.

DRUG INTERACTIONS :
Guanethidine and other adrenergic neuron blockers: Olanzapine Film-Coated Tablet (Olzadin) may reduce the antihypertensive actions of these drugs.
Tricyclic Antidepressants and other antiparkinsonian drugs: Olanzapine Film-Coated Tablet (Olzadin) may potentiate the adverse effects of these drugs when given concomitantly.
Metoclopramide: Concomitant administration of this drug may increase the risk of antipsychotic-induced extrapyramidal effects.
Alcohol: Akathisia and dystonia occurred after consumption of alcohol by patient taking antipsychotics.
Antiarrhythmics, antihistamine, antimalarial, and cisapride; diuretics that cause electrolyte imbalance particularly hypokalemia: Antipsychotic drugs may increase the risk of arrhythmias when given with other drugs which prolong QT interval.
Antiepileptics: May decrease plasma concentrations of antipsychotics and their active metabolites.
Cytochrome P450 isoenzyme CYP1A2: The metabolism of olanzapine is mediated to some extent by the cytochrome P450 isoenzyme CYP1A2. Concomitant administration of drugs which inhibit or act as a substrate to this isoenzyme may affect plasma concentrations of olanzapine.

ADVERSE EFFECTS:
General disorders: somnolence, dizziness, edema
Metabolism disorders: weight gain, increased appetite
Cardiovascular system disorder: orthostatic hypotension
Urogenital system disorders: asymptomatic hyperprolactinemia, priapism
Hemic and lymphatic system disorders: agranulocytosis, neutropenia
Nervous system disorders: extrapyramidal symptoms including tardive dyskinesia more likely at high doses, mania, Neuroleptic Malignant Syndrome (NMS), convulsion

"For suspected adverse drug reaction, report to FDA: www.fda.gov.ph.
Seek medical attention immediately at first sign of any adverse drug reaction."

PREGNANCY AND LACTATION:
Pregnancy Category C - Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Nursing mothers receiving Olanzapine Film-Coated Tablet (Olzadin) should discontinue breastfeeding because it is excreted in breast milk.

OVERDOSE AND MANAGEMENT:
Symptoms of overdose may include agitation, dysarthria, and tachycardia. There is a potential risk for medically serious reactions such as aspiration, cardiopulmonary arrest, cardiac arrhythmias, delirium, possible neuroleptic malignant syndrome, respiratory depression/arrest, convulsion, hypertension, and hypotension.

The possibility of multiple drug involvement should be considered. In case of acute overdosage, establish and maintain an airway and ensure adequate oxygenation and ventilation, which may include intubation. Gastric lavage (after intubation, if patient is unconscious) and administration of activated charcoal together with a laxative should be considered. The administration of activated charcoal (1 g) reduces the Cmax and AUC of oral olanzapine by about 60%. As peak olanzapine levels are not typically obtained until about 6 hours after dosing, charcoal may be a useful treatment for olanzapine overdose.

The possibility for obtundation, seizures, or dystonic reaction of the head and neck following overdose may create a risk of aspiration with induced emesis. Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias.

There is no specific antidote to olanzapine; therefore, appropriate supportive measures should be initiated. Hypotension and circulatory collapse should be treated with appropriate measures such as intravenous fluids and/or sympathomimetic agents (Do not use epinephrine, dopamine, or other sympathomimetic agents with beta-agonist activity, since beta stimulation may worsen hypotension in the setting of olanzapine-induced alpha blockade.) Close medical supervision and monitoring should continue until the patient recovers.

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

STORAGE CONDITION:
Store at temperatures not exceeding 30ºC.
Keep out of reach of children.

AVAILABILITY:
Olanzapine 5 mg Film-Coated Tablet (Olzadin)……Alu-PVC White Opaque Blister x 10's (Box x 30's)
Registration No.: DR-XY41187
Date of First Authorization: September 2012

Olanzapine 10 mg Film-Coated Tablet (Olzadin)……Alu-PVC White Opaque Blister x 10's (Box x 30's)
Registration No.: DR-XY41242
Date of First Authorization: September 2012

Date of Revision of Package Insert: February 2017

Manufactured for:
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