Summary of prescribing information for OLIZA tablets

Active Ingredient: Each uncoated tablet of OLIZA contains: olanzapine 2.5, 5, 7.5 10, 15, & 20 mg. **Indication:** For treatment of schizophrenia in adults. **Dosage:** Oral olanzapine should be administered on a once-a-day schedule without regard to meals. Start at 5-10 mg once daily; Target: 10 mg/day within several days. Further dosage adjustments, if indicated, should generally occur at intervals of not less than 1 week. The safety of doses above 20 mg/day has not been evaluated in clinical trials. **Contraindications:** Hypersensitivity to any component of the product; Patients with known risk of narrow angle glaucoma. **Warning and precautions:** Elderly Patients with Dementia-Related Psychosis: Increased risk of death and increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack). Suicide: The possibility of a suicide attempt is inherent in schizophrenia and in bipolar I disorder, and close supervision of high-risk patients should accompany drug therapy; when using in combination with fluoxetine. Neuroleptic Malignant Syndrome: Manage with immediate discontinuation. Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS): Discontinue if DRESS is suspected. Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes including hyperglycemia, dyslipidemia, and weight gain. Hyperglycemia and Diabetes Mellitus: In some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients taking olanzapine. Dyslipidemia: Undesirable alterations in lipids have been observed. Weight Gain: Potential consequences of weight gain should be considered. 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 caution in patients with cardiovascular disease, cerebrovascular disease, and those conditions that could affect hemodynamic responses. Leukopenia, Neutropenia, and Agranulocytosis: Has been reported with antipsychotics, including olazapine. Seizures: Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold. Potential for Cognitive and Motor Impairment: Has potential to impair judgment, thinking, and motor skills. Use caution when operating machinery. Hyperprolactinemia: May elevate prolactin levels. Laboratory Tests: Monitor fasting blood glucose and lipid profiles at the beginning of, and periodically during, treatment. **Pregnancy & Lactation:** Pregnancy Category C. Lactation: Excreted in breast milk. **Interaction:** Diazepam: May potentiate orthostatic hypotension; Alcohol: May potentiate orthostatic hypotension; Carbamazepine: Increased clearance of olanzapine; Fluvoxamine: May increase olanzapine levels; Olanzapine and Fluoxetine in Combination: Also refer to the Drug Interactions section of the package insert of FDC. CNS Acting Drugs: Caution should be used when taken in combination with other centrally acting drugs and alcohol; Antihypertensive Agents: Enhanced antihypertensive effect; Levodopa and Dopamine Agonists: May antagonize levodopa/dopamine agonists; Lorazepam (IM): Increased somnolence with IM olanzapine; Other Concomitant Drug Therapy: When using olanzapine in combination with lithium or valproate, refer to the Drug Interactions sections of the package insert for those products. **Adverse reactions:** common: dizziness, constipation, personality disorder (i.e., nonaggressive objectionable behavior, weight gain, postural hypotension, and akathisia, somnolence, dry mouth, asthenia, dyspepsia, increased appetite, and tremor, back pain, speech disorder, increased salivation, amnesia, and paresthesia.

Overdose:

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It is recommended to refer full prescribing information before prescription.

For further medical information, please write to: Intas Pharmaceuticals Ltd., Corporate House, Near Sola Bridge, SG highway, Thaltej, Ahmedabad-380054, Gujarat, India. productqueries@intaspharma.com