

TOLAZ-MD

For the use of a Psychiatrist Only

Abbreviated Prescribing information for TOLAZ-MD [Olanzapine 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg Orally Disintegrating Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Exact mechanism is unknown. Efficacy in schizophrenia is mediated through a combination of dopamine and serotonin type 2 (5HT₂) antagonisms.

INDICATION: Schizophrenia; Bipolar Disorder.

DOSAGE AND ADMINISTRATION: Immediately after opening the blister, using dry hands remove tablet and place entire tablet in the mouth. Tablet disintegration occurs rapidly in saliva so it can be easily swallowed with or without liquid. Alternatively, it may be dispersed in a full glass of water or other suitable beverage (orange juice, apple juice, milk or coffee) immediately before administration. **Schizophrenia:** 5 to 10 mg initially with once a daily schedule, whenever dosing adjustment necessary dose increments/decrements of 5 mg QD are recommended. 5mg starting dose in debilitating patients. Maintenance dose of 10mg to 20mg dose is recommended. **Bipolar Disorder:** Beginning with 10 to 15mg dose, whenever dosing adjustment necessary dose increments/decrements of 5 mg QD are recommended. As maintenance therapy 5 to 20 mg/day recommended.

CONTRAINDICATION: Olanzapine is contraindicated in patients with a known hypersensitivity to the product. Narrow angle glaucoma.

WARNINGS & PRECAUTIONS: Other antipsychotics, underlying condition which may prevail hypotension, dementia-related psychosis and/or behavioural disturbances, cerebrovascular adverse events, including stroke, in elderly patients with dementia, parkinson's disease, neuroleptic malignant syndrome, metabolic changes (hyperglycaemia, diabetes, lipid alterations), anticholinergic activity, elevation of hepatic enzymes, leukopenia, neutropenia, agranulocytosis, QT interval prolongation, thromboembolism, CNS active drugs, seizures, tardive dyskinesia, sudden cardiac death, cautious while driving machinery, disruption of body temperature regulation mechanism, dysphagia, suicidal attempt/ideation, hyperprolactinemia, cognitive and motor impairment. Tolaz LA contains lactose.

DRUG INTERACTIONS: CNS active drugs including other antipsychotics; agents that induce CYP1A2 or glucuronyl transferase enzymes (e.g. omeprazole and rifampin), carbamazepine, ethanol, fluoxetine, fluvoxamine, intravenous lorazepam, antihypertensive agents, levodopa and dopamine agonists.

ADVERSE REACTIONS: Somnolence, respiratory depression, hypotension, bradycardia, sudden cardiac death, tachycardia, syncope, sinus pause, injection site reaction, weight gain, eosinophilia, elevated prolactin, cholesterol, glucose and triglyceride levels, glucosuria, increased appetite, dizziness, akathisia, parkinsonism, dyskinesia, orthostatic hypotension, anticholinergic effects, transient asymptomatic elevations of hepatic-aminotransferases, rash, asthenia, fatigue, oedema, allergic reaction, hypothermia, dystonia, tardive dyskinesia, ventricular tachycardia, fibrillation, elevated lipid levels, akathisia, dyskinesia, parkinsonism, constipation, dry mouth, photosensitivity reaction, rhabdomyolysis, drug withdrawal syndrome neonatal, priapism.

MARKETED BY:



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IN/TOLAZ-MD 2.5, 5, 7.5, 10, 15, 20mg /Jul-15/01/AbPI

(Additional information is available on request)