

TOLAZ INJECTION

For the use of a Psychiatrist or a Hospital or a Laboratory Only

Abbreviated Prescribing information for TOLAZ INJECTION [Olanzapine for Injection 10 mg (Lyophilized)] [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: Agitation Associated with Schizophrenia and Bipolar I Mania.

DOSAGE AND ADMINISTRATION: Recommended dose is 10mg, lower dose also can be given. If required additional 10mg dose also can be administered. Elderly patient 5mg per injection should be considered and it can be lowered based on the underlined condition to 2.5mg. Olanzapine for injection should not be administered intravenously or subcutaneously. It should be injected slowly, deep into the muscle mass. Re-constituted injection should be used within 1 hour and discard any un-used portion. Do not use if visible particulates seen.

CONTRAINDICATION: Olanzapine for injection is contraindicated in patients with a known hypersensitivity to olanzapine or any of its components.

WARNINGS & PRECAUTIONS: Use cautiously in unstable medical conditions (acute MI, unstable angina pectoris, severe hypotension and/or bradycardia, sick sinussyndrome, or following heart surgery), other antipsychotics, underlying condition which may prevail hypotension, dementia-related psychosis and/or behavioural disturbances, parkinson's disease, neuroleptic malignant syndrome, metabolic changes (hyperglycaemia, diabetes, lipid alterations), anticholinergic activity, elevation of hepatic enzymes, neutropenia, 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.

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.

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 INJECTION 10mg/Jul-15/01/AbPI

(Additional information is available on request)