

TOLAZ SPRINKLE

For the use of a Psychiatrist Only

Abbreviated Prescribing information for TOLAZ SPRINKLE [Olanzapine Powder 5mg/g] [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: **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. Empty the packet contents by sprinkling into a small cup containing about 30 ml boiled and cooled water (six teaspoonful water). Stir well and drink the solution immediately. Add more water to rinse the cup and drink the water.

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

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, 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, hyperprolactinemia, cognitive and motor impairment.

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 SPRINKLE 5mg/g/Jul-15/01/AbPI
(Additional information is available on request)