

## LOZAPIN

### For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for LOZAPIN [Clozapine Tablets 25mg, 50mg, 100mg] [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** It has been proposed that the therapeutic efficacy of clozapine in schizophrenia is mediated through antagonism of the dopamine type 2 (D2) and the serotonin type 2A (5-HT<sub>2A</sub>) receptors. Clozapine also acts as an antagonist at adrenergic, cholinergic, histaminergic and other dopaminergic and serotonergic receptors.

**INDICATION:** Indicated in the management of Schizophrenic patients.

**DOSAGE AND ADMINISTRATION:** LOZAPIN 25mg, 50mg and 100mg Uncoated tablets should be taken as directed by Physician.

**CONTRAINDICATION:** Hypersensitivity to the active substance, History of toxic or idiosyncratic granulocytopenia History of LOZAPIN-induced agranulocytosis, Impaired bone marrow function, Uncontrolled epilepsy, Alcoholic and other toxic psychoses, drug intoxication, comatose conditions, • Circulatory collapse and/or CNS depression of any cause, Severe renal or cardiac disorders (e.g. myocarditis). Active liver disease associated with nausea, anorexia or jaundice; progressive liver disease, hepatic failure and Paralytic ileus.

**WARNINGS & PRECAUTIONS:** Elderly patients with dementia related psychosis; agranulocytosis; risk of orthostatic hypotension, bradycardia, and syncope during initiation of therapy; seizures, myocarditis, cardiomyopathy; Increased Mortality in Elderly Patients with Dementia-Related Psychosis; eosinophilia, QT interval prolongation, metabolic changes (hyperglycemia and diabetes mellitus, dyslipidemia, weight gain), neuroleptic malignant syndrome, fever, pulmonary embolism, anticholinergic toxicity, interference with cognitive and motor performance, tardive dyskinesia, cerebrovascular adverse events like (stroke, transient ischemic attack), recurrence of psychosis and cholinergic rebound after abrupt discontinuation of clozapine, pregnancy and lactation.

**DRUG INTERACTIONS:** Bone marrow suppressants (e.g. carbamazepine, chloramphenicol), sulphonamides (e.g. co-trimoxazole), pyrazolone analgesics (e.g. phenylbutazone), penicillamine, cytotoxic agents and long-acting depot injections of antipsychotics. Benzodiazepines, Anticholinergics, Antihypertensives, Alcohol, MAOIs, CNS depressants, including narcotics and benzodiazepines highly protein bound substances (e.g. warfarin and digoxin). Phenytoin, Lithium, CYP1A2 inducing substances (e.g. omeprazole), CYP1A2 inhibiting substances e.g. fluvoxamine, caffeine, ciprofloxacin, perazine or hormonal contraceptives (CYP1A2, CYP3A4, CYP2C19).

**ADVERSE REACTIONS:** Leukopenia/decreased WBC/neutropenia, eosinophilia, leukocytosis, Agranulocytosis, Anaemia, Thrombocytopenia, thrombocythaemia, Angioedema, Drug rash with eosinophilia and systemic symptoms (DRESS), Pseudophaeochromocytoma, Weight gain, Diabetes mellitus, impaired glucose tolerance, obesity, Hyperosmolar coma, ketoacidosis, severe hyperglycaemia, hypercholesterolemia, hypertriglyceridemia, Dysarthria, Dysphemia, Agitation, restlessness, Drowsiness/sedation, dizziness, Seizures, extrapyramidal symptoms, akathisia, tremor, rigidity, headache, Neuroleptic malignant syndrome, Confusion, delirium, Tardive dyskinesia, obsessive compulsive symptoms, Cholinergic syndrome, Blurred vision, Tachycardia, ECG changes, Circulatory collapse, arrhythmias, myocarditis, pericarditis/ pericardial effusion, Cardiomyopathy, cardiac arrest, Myocardial infarction, myocarditis, chest pain/angina pectoris, atrial fibrillation, palpitations, mitral valve incompetence associated with clozapine related cardiomyopathy, Syncope, postural hypotension, hypertension, Thromboembolism, Respiratory depression/arrest, Pleural effusion, Constipation, hypersalivation, Nausea, vomiting, anorexia, dry mouth, Dysphagia, Intestinal obstruction, Diarrhea, Elevated liver enzymes, Pancreatitis, hepatitis, cholestatic jaundice, Fulminant hepatic necrosis, Skin reactions, Pigmentation disorder, Rhabdomyolysis\*, muscle weakness, Urinary retention, Tubulointerstitial nephritis, Renal failure, Drug withdrawal syndrome neonatal, Priapism, Retrograde ejaculation, Benign hyperthermia, fever and fatigue.

**MARKETED BY:**



**IN/ LOZAPIN 25mg, 50mg, 100mg/APR-2022/03/ABPI**

(Additional information is available on request)