ABRIDGED PRESCRIBING INFORMATION: SKIZORIL ER

COMPOSITION: Clozapine Extended Release Capsules 12.5 mg, 25 mg, 50 mg 100 mg and 200 mg **INDICATIONS:** Skizoril ER is Indicated in the management of schizophrenic patients. **DOSAGE AND ADMINISTRATION:** Starting therapy 12.5 mg once a day, followed by 25 mg once a second day. If well tolerated, the daily dose may then be increased slowly in increments of 25 to 50 mg in order to achieve a dose level of up to 200 mg/day within 2 to 3 weeks. Thereafter, if required, the daily dose may be further increased in increments of 50 to 100 mg at half-weekly or, preferably, weekly intervals. **CONTRAINDICATIONS:** Clozapine is contraindicated in patients with hypersensitivity to the drug or its excipients, those unable to undergo regular blood tests, individuals with a history of toxic or idiosyncratic granulocytopenia/agranulocytosis (excluding that from previous chemotherapy), prior clozapine-induced agranulocytosis, impaired bone marrow function, uncontrolled epilepsy, severe psychiatric conditions including alcoholic psychosis and drug intoxication, circulatory collapse or CNS depression, severe renal or cardiac disorders, active liver disease with associated symptoms, and paralytic ileus, and it should not be used concurrently with medications known to significantly increase the risk of agranulocytosis. **WARNINGS AND PRECAUTIONS** Clozapine can cause agranulocytosis. The incidence of agranulocytosis and the fatality rate in those developing agranulocytosis have decreased markedly since the institution of white blood cell (WBC) counts and absolute neutrophil count (ANC) monitoring. WBC and differential blood counts must be performed within 10 days prior to initiating Clozapine treatment to ensure that only patients with normal WBC counts and ANC (WBC count ≥ 3500/mm3 (≥ 3.5x 109/L) and ANC ≥ 2000/mm3 (≥ 2.0 x 109/L) will receive Clozapine. **USE IN SPECIFIC POPULATIONS: Patients aged 60 years and older:** Initiation of treatment in patients aged 60 years and older is recommended at a lower dose. Patients with stable pre-existing liver disorders may receive Clozapine, but need regular liver. Data from two large observational studies showed that elderly people with dementia who are treated with antipsychotics are at a small increased risk of death compared with those who are not treated. For clozapine, there are only limited clinical data on exposed pregnancies. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. **DRUG INTERACTIONS:** Long-acting depot antipsychotics (which have myelosuppressive potential) must not be used concurrently with Clozapine because these cannot be rapidly removed from the body in situations where this may be required, e.g. neutropenia. Alcohol should not be used concomitantly with Clozapine due to possible potentiation of Sedation. Concomitant administration of medicinal products known to induce cytochrome P450 enzymes may decrease the plasma levels of clozapine, leading to reduced efficacy. Concomitant use of lithium or other CNS-active substances may increase the risk of development of neuroleptic malignant syndrome (NMS). **ADVERSE REACTIONS:** The most serious adverse reactions experienced with clozapine are agranulocytosis, seizure, cardiovascular effects and fever. The most common side effects are drowsiness/sedation, dizziness, tachycardia, constipation, and hypersalivation. **OVERDOSE:** Most of the fatalities were associated with cardiac failure or pneumonia caused by aspiration and occurred at doses above 2000 mg. There have been reports of patients recovering from an overdose in excess of 10 000 mg. **SHELF LIFE**: 2 years **STORAGE:** Store at 20-25°C (68°-77°F).

FOR FURTHER INFORMATION, PLEASE REFER FULL PRESCRIBING INFORMATION. Revised as on 27th November 2024.