For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information
VINLEP®
Oxcarbazepine Tablets IP

COMPOSITION: Vinlep 150, 300, 450, 600: Each film coated tablet contains oxcarbazepine IP 150mg, 300mg, 450mg, 600 mg respectively.

THERAPEUTIC INDICATIONS s
Monotherapy and adjunctive therapy in the treatment of partial seizures (which include seizure subtypes of simple, complex and partial seizures evolving to secondarily generalized seizures) in adult patients. Treatment of generalized tonic-clonic seizures in adults and children. Adjunctive therapy in the treatment of partial seizures in children aged 4 -16 years. Monotherapy in the treatment of partial seizures in children aged 4-16 years. Vinlep can replace other anti-epileptic drugs when current therapy provides insufficient seizure control.

DOSAGE AND ADMINISTRATION
Vinlep is suitable for use either as monotherapy or in combination with other antiepileptic drugs. In mono and adjunctive therapy treatment with Vinlep is initiated with a clinically effective dose given in two divided doses. The dose maybe increased depending on the clinical response of the patient. *Adults and elderly patients*: Monotherapy and adjunctive therapy- Treatment should be initiated with a dose of 600mg/day (8-10 mg/kg/day) given in 2 divided doses. Good therapeutic effects are seen at doses between 600mg/day and 2400 mg/day. Dose may be increased by a maximum of 600mg/day increments at weekly intervals. *Pediatric Patients:* In mono- and adjunctive therapy, Vinlep should be initiated with a dose of 8-10 mg/kg/day given in 2 divided doses. Dose may be increased by a maximum of 10 mg/kg/day increments to a maximum daily dose of 60mg/kg/day. *Geriatric patients: (65 years old and above)*: No special dose recommendations are necessary in elderly patients because therapeutic doses are individually adjusted.

SAFETY-RELATED INFORMATION
Contraindications: Hypersensitivity to the active substance, oxcarbazepine or to any of the excipients.
Warnings and Precautions: ***Hypersensitivity***: Drug should be discontinued and alternative treatment started. ***Dermatological effects***: includes Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme have been reported very rarely. Median time to onset was 19 days. Discontinue Vinlep and prescribe another anti-epileptic drug. ***Association with HLA***-B*1502 :There is growing evidence that different Human Leukocyte Antigen (HLA) alleles play a role in association with adverse cutaneous reactions in predisposed patients. As the chemical structure of oxcarbazepine is similar to that of carbamazepine, there is a possibility that patients carrying the HLA-B*1502 allele also have an increased risk of SJS/TEN skin reactions with oxcarbazepine. The use of Vinlep should be avoided in tested patients who are found to be positive for HLA-B*1502 unless the benefits clearly outweigh the risks. Association with HLA-A*3101- Human Leukocyte Antigen (HLA)-A*3101 may be a risk factor for the development of cutaneous adverse drug reactions such as SJS, TEN, DRESS, AGEP and maculopapular rash. Genetic screening is generally not recommended for any current Vinlep user as the risk of SJS/Ten, AGEP, DRESS and maculopapular rash is largely confined to the first few months of therapy, regardless of HLA-A*3101 status.
Limitation of genetic screening-Genetic screening results must never substitute for appropriate clinical vigilance and patient management. ***Hyponatraemia***: Serum sodium levels below 125mmol/L, usually asymptomatic and not requiring adjustment of therapy have been observed in up to 2.7% of treated patients. In patients with pre-existing renal conditions associated with low sodium or in patients treated concomitantly with sodium-lowering medicinal products, serum sodium levels should be measured prior to therapy, thereafter two weeks and monthly intervals for first three months. Patients with cardiac insufficiency and secondary heart failure should have regular weight measurements. In case of fluid retention or worsening of the cardiac condition, serum sodium should be checked. ***Hepatic function***: Discontinue Vinlep in case of suspected hepatitis. ***Hematological effect:*** Discontinue drug if any evidence of significant bone marrow depression. ***Suicidal ideation and behavior:*** Patients should be monitored for signs of suicidal ideation and behavior and appropriate treatment should be considered. ***Hormonal contraceptives***: Treatment with Vinlep may render the contraceptive ineffective, non-hormonal forms of contraception are recommended. ***Alcohol:*** Possible additive sedative effect, exercise caution. *Drug discontinuatio*n– Withdraw gradually to minimize potential of increased seizure frequency. ***Driving and using machines:*** Patients should exercise due caution when driving a vehicle or operating machinery.

Pregnancy & Lactation: Offspring of epileptic mothers are known to be more prone to developmental disorders, including malformations. Potential benefits must be carefully weighed against the potential risk of foetal malformations especially in first three months of pregnancy. Minimum effective dose should be given. Monotherapy should be administered whenever possible. Patients should be counselled regarding the increased risk of malformations. Effective antiepileptic treatment should not be interrupted since aggravation of illness is detrimental to both the mother and foetus. Folic acid supplementation recommended during pregnancy. As a precaution Vitamin K1 should be administered as preventive measure in the last few weeks of pregnancy and to the newborn. Vinlep should not be used during breast feeding. Prenatal exposure to oxcarbazepine monotherapy results in children being born small for gestational age (SGA; defined as birth weight below the 10th percentile for their sex and gestational age) following prenatal exposure to oxcarbazepine monotherapy.

Adverse Reactions: The most commonly reported adverse reactions are somnolence, headache, dizziness, diplopia, nausea, vomiting and fatigue occurring in more than 10 % of patients.

For full prescribing information, please contact Sanofi Healthcare India Private Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Updated: Dec 2025

Source: Oxcarbazepine CCDS v2 dated 16th Oct 2025