NOVARTIS

TRILEPTAL® (oxcarbazepine)

300 mg and 600 mg Film-coated Tablets

Basic Succinct Statement

Version 2.2

Code: BSS RD 17 JUL 2017, APPR 18 APR 2018

This material is only meant for Healthcare Professionals

TRILEPTAL®

Important note: Before prescribing, consult full prescribing information.

Presentation: Film-coated tablets containing 300 mg or 600 mg oxcarbazepine.

Indications: Epilepsy: partial seizures or generalized tonic-clonic seizures.

Dosage: Adults and elderly: 600 to 2400 mg/day**. Children:** 8 to 10 mg/kg/day. Administration in 2 divided doses. Trileptal has not been studied in controlled clinical trials in children below 2 years of age. Dosage adjustment needed in patients with impaired renal function.

Contraindications: Known hypersensitivity to oxcarbazepine or eslicarbazepine or any of the excipients of Trileptal.

Warnings/Precautions: ♦Caution in case of hypersensitivity (including multi-organ hypersensitivity) to carbamazepine ♦Risk of anaphylaxis and angioedema ♦Serious dermatological reactions (Trileptal should be discontinued). Potential association of SJS/TEN with the presence of the HLA-B*1502 and the HLA-A*3101 alleles. Initial testing for the HLA-B*1502 allele should be considered in patients at increased risk due to their genetic background (e.g. patients with Chinese ancestry). In patients who test positive, Trileptal should be avoided, unless benefits clearly outweigh risks. There is insufficient data to support a recommendation for initial testing for the HLA-A*3101 allele. ♦Risk of seizure aggravation. Caution especially in children but may also occur in adults ♦Risk of hyponatraemia (caution especially in patients with pre-existing renal conditions associated with low sodium level or patients on sodium lowering co-medication. Caution in patients with cardiac insufficiency and secondary heart failure; in case of fluid retention or worsening of the cardiac condition, serum sodium should be checked). ♦Risk of Hypothyroidism. Thyroid function monitoring is recommended in the pediatric age group, especially in children aged two years or below; before and during treatment with Trileptal. ♦Caution in case of hepatitis and in patients with severe hepatic impairment. ♦Caution in patients with impaired renal function (creatinine clearance less than 30 mL/min). ♦Caution in case of adverse hematological reactions. Discontinuation of the drug should be considered if any evidence of significant bone marrow depression develops. ♦Caution in case of suicidal ideation or behavior. ♦Caution in women taking hormonal contraceptives during treatment with Trileptal. ♦Discontinuation of treatment should be done gradually. ♦Caution when combined with alcohol, and when driving or operating machines. ♦Use during pregnancy: the potential benefits should be carefully weighed against the potential risks to the fetus; clinical response to be monitored and determination of changes in MHD (active metabolite) plasma concentration should be considered ♦Should not be used during breast-feeding.

Interactions: Felodipine, oral contraceptives, antiepileptics (e.g. carbamazepine, phenobarbital, phenytoin), immunosuppressants (e.g. ciclosporin), enzyme inducing drugs (e.g. rifampicin). Check full Product Insert for complete list of interactions.

Adverse reactions: ♦***Very common:*** somnolence, headache, dizziness, diplopia, vomiting, nausea, fatigue. ♦***Common:*** weight increased, asymptomatic hyponatraemia, agitation, affect lability, confusional state, depression, apathy, ataxia, tremor, nystagmus, disturbance in

attention, amnesia, vision blurred, visual disturbance, vertigo, diarrhoea, abdominal pain, constipation, rash, alopecia, acne, asthenia. ♦***Common*** (in children aged 1 month to less than 4 years): ataxia, irritability, vomiting, lethargy, fatigue, nystagmus, tremor, decreased appetite and blood uric acid increased. ♦***Uncommon:*** leucopenia, urticaria, hepatic enzymes increased, blood alkaline phosphatase increased. ♦***Very rare:*** bone marrow depression, aplastic anemia, agranulocytosis, pancytopenia, thrombocytopenia, neutropenia, anaphylactic reactions, hypersensitivity (including multi-organ hypersensitivity), hypothyroidism, symptomatic hyponatraemia, atrioventricular block, arrhythmia, hypertension, pancreatitis and/or lipase and/or amylase increase, hepatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), angioedema, erythema multiforme, systemic lupus erythematosus, Amylase increase, lipase increase. ♦***Unknown:*** Inappropriate ADH secretion like syndrome with signs and symptoms of lethargy, nausea, dizziness, decrease in serum (blood) osmolality, vomiting, headache, confusional state or other neurological signs and symptoms. Drug rash with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP), fall, speech disorders (including dysarthria), decreased bone mineral density, osteopenia, osteoporosis and fractures in patients on long-term therapy with Trileptal