NOVARTIS

TEGRETOL®

(carbamazepine)

200 mg tablets
200 mg and 400 mg CR tablets
100 mg / 5 mL oral suspension

Basic Succinct Statement

Version 2.2

Code: BSS RD 1 DEC 2017; APPR 27 JUL 2018

This material is only meant for Healthcare Professionals

TEGRETOL®

Important note: Before prescribing, consult full prescribing information.

Presentation: Carbamazepine tablets of 200 mg; CR tablets (divisible) of 200 and 400 mg; oral suspension 100 mg/5 mL.

Indications: Oral forms: Epilepsy (except absences and myoclonic seizures) in monotherapy and combination therapy. Acute mania; maintenance treatment of bipolar affective disorders to prevent or attenuate recurrence. Alcohol withdrawal syndrome. Trigeminal neuralgia, idiopathic glossopharyngeal neuralgia.

Dosage: Administration in divided doses. Adults 100 to 1600 mg/day depending on indication and severity of illness (maximum dose 2000 mg/day in epilepsy and 1200 mg/day in trigeminal neuralgia). Children: 10 to 20 mg/kg/day (maximum dose up to 6 years of age: 35 mg/kg/day; 6-15 years of age: 1000 mg/day; >15 years of age: 1200 mg/day).

Contraindications: Hypersensitivity to carbamazepine or structurally related compounds or any other component of the formulation. Atrioventricular block. History of bone-marrow depression. History of hepatic porphyrias. Concomitant use of MAOIs.

Warnings and Precautions: Initial and periodic complete blood counts, liver function tests and urine analysis. Potential association of SJS/TEN with the presence of the HLA-B*1502 and the HLA-A*3101 alleles. Initial testing for HLA-B*1502 allele should be considered in patients at increased risk due to their genetic background (e.g. patients with Chinese ancestry). Initial testing for the HLA-A*3101 allele should be considered in patients at increased risk due to their genetic background (e.g. patients with Japanese, Caucasian, indigenous of the Americas, Hispanic, southern of India and Arabic ancestry). In patients who test positive, Tegretol should be avoided unless benefits clearly outweigh risks. Monitoring of plasma levels. Caution in case of history of cardiac, hepatic, or renal damage and adverse hematological reactions. Caution in case of adverse hematological reactions, serious skin reactions (e.g. SJS/TEN), allergic skin reactions, hypersensitivity reactions (including Drug Rash with Eosinophilia and Systemic Symptoms [DRESS] involving multiple organs), mixed seizures, liver disease , hyponatremia, hypothyroidism. Caution in case of pre-existing increased intraocular pressure, latent psychosis, confusion and agitation in the elderly, in women taking hormonal contraceptives (non-hormonal forms of contraception are recommended). Caution in case of suicidal ideation or behaviour. No abrupt withdrawal of Tegretol. Caution with oral suspension which contains sorbitol and parahydroxybenzoates. Caution when driving or operating machines. Tegretol treatment may cause ataxia, dizziness, somnolence, hypotension, confusional state, sedation which may lead to falls and consequently, fractures or other injuries.

Pregnancy, lactation, females and males of reproductive potential

Pregnancy: Carbamazepine may be associated with fetal harm when administered to a pregnant woman. Tegretol should be used during pregnancy only if the potential benefit justifies the potential risks.

Adequate counselling should be made available to all pregnant women and women of childbearing potential, regarding the risks associated with pregnancy due to potential teratogenic risk to the fetus.

Risk of neonatal withdrawal syndrome.

Contraception: Women of childbearing potential should use effective contraception during treatment with carbamazepine and for 2 weeks after the last dose.

Lactation: Benefits of breast-feeding to be weighed against remote possibility of adverse effects (including hepatobiliary) occurring in the infant.

Adverse reactions: Mild side effects mostly transient and dose dependent.

Very common: dizziness, ataxia, fatigue, drowsiness, allergic skin reactions, leukopenia, nausea, vomiting, increased gamma-GT.

Common: edema, fluid retention, weight increase, hyponatremia and blood osmolarity decreased due to an antidiuretic hormone (ADH)-like effect leading in rare cases to water intoxication accompanied by lethargy, vomiting, headache, confusional state, neurological disorders; headache, accommodation disorders, diplopia, liver enzyme elevations, thrombocytopenia, eosinophilia, dry mouth, increased blood alkaline phosphatase, dermatitis allergic, urticaria which may be severe.

Other less frequent but serious undesirable effects.

Uncommon: exfoliative dermatitis.

Rare: Jaundice, hepatitis, delayed multi-organ hypersensitivity disorders, systemic lupus erythematosus, depression.

Very rare: neuroleptic malignant syndrome, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN; also known as Lyell's syndrome), blood dyscrasias, hepatic porphyria, pancreatitis, anaphylactic reaction, angioedema, AV-block with syncope, congestive heart failure, cardiac conduction disorders, aggravation of coronary artery disease, thromboembolism, renal dysfunction, interstitial nephritis, hepatic failure, aseptic meningitis, activation of psychosis.

Unknown (Adverse reaction from spontaneous report): Reactivation of human herpes virus 6 infection, bone marrow failure, fall (associated with Tegretol treatment induced ataxia, dizziness, somnolence, hypotension, confusional state, sedation), sedation, memory impairment colitis, Drug Rash with Eosinophilia and Systemic Symptoms (DRESS), Acute Generalized Exanthematous Pustulosis (AGEP), lichenoid keratosis, onychomadesis, fracture, bone density decreased.

This is not the complete list of ADRs. See full Prescribing Information.

Interactions: Carbamazepine is a powerful enzyme inducer. Cautious concomitant use of cytochrome P450 3A4 inducers or inhibitors. Clinically important interactions with other drugs/substances (incl. hormonal contraceptives, alcohol) are common.