Intermediate Prescribing Information

℞ TEGRETOL® *(carbamazepine tablets)*

TEGRETOL® 200 mg

℞ TEGRETOL Chewtabs®

(carbamazepine chewable tablets)

TEGRETOL® Chewtabs™ 100 mg
TEGRETOL® Chewtabs™ 200 mg

℞ TEGRETOL® CR

(carbamazepine controlled release tablets)

TEGRETOL® CR 200 mg TEGRETOL® CR 400 mg

Anticonvulsant
For symptomatic relief of trigeminal neuralgia
Antimanic

INDICATIONS A. Management of psychomotor (temporal lobe) epilepsy. As an adjunct in some patients with secondary or partial epilepsy with complex symptomatology or secondarily generalized seizures, when combined with other antiepileptic agents.
As an alternative in patients with generalized tonic-clonic seizures and marked side effects or who fail to respond to other anticonvulsant drugs.
Ineffective for controlling petit mal, minor motor, myoclonic and predominantly unilateral seizures, and does not prevent generalization of epileptic discharge. Exacerbation of seizures may occur in patients with atypical absences.
B. Symptomatic relief of pain of true or primary trigeminal neuralgia (tic douloureux). Not for prophylactic use. Glossopharyngeal neuralgia has been relieved in some patients. Other measures must be considered for patients failing to respond or who are sensitive to TEGRETOL.
C. Treatment of Acute Mania and Prophylaxis in Bipolar (Manic-Depressive) Disorders: may be used as monotherapy or adjunct to lithium in patients who are resistant to or are intolerant of conventional antimanics. Possibly an alternative to neuroleptics in such patients. Patients with severe mania, dysphoric mania or rapid cycling who are non-responsive to lithium may respond positively to carbamazepine. Recommendations are based on extensive clinical experience and some comparative trials.

CONTRAINDICATIONS History of hepatic disease, acute intermittent porphyria or serious blood disorder, in patients with AV heart block (see Precautions), hypersensitivity to carbamazepine or to tricyclic compounds, or their analogues or metabolites.
Do not give with, immediately before or immediately after treatment with monoamine oxidase inhibitors. There should be as long a drug free interval as the clinical condition allows, in no case less than 14 days. Then TEGRETOL dosage should be low initially, increased very gradually.

WARNINGS ***Although reported infrequently, serious adverse effects have been observed during use of TEGRETOL (carbamazepine). Agranulocytosis and aplastic anemia have occurred in a few instances with a fatal outcome. Leucopenia, thrombocytopenia, hepatocellular and cholestatic jaundice, and hepatitis also reported. It is important that TEGRETOL be used carefully and close clinical and frequent laboratory supervision be maintained throughout treatment to detect signs and symptoms of possible blood dyscrasia, as early as possible. Discontinue TEGRETOL if any evidence of significant bone marrow depression appears. (See "PRECAUTIONS"). Should signs and symptoms suggest a severe skin reaction such as Steven-Johnson syndrome or Lyell's syndrome, withdraw TEGRETOL at once. Long-term toxicity studies in rats indicated a potential carcinogenic risk. Weigh possible risk of TEGRETOL against potential benefits before prescribing.***

Pregnancy and nursing: Women with epilepsy who are, or intend to become pregnant, should be treated with special care.
In women of childbearing potential, TEGRETOL (carbamazepine) should, whenever possible, be prescribed as monotherapy, because the incidence of congenital abnormalities in offspring of women treated with more than one antiepileptic drug is greater than in those receiving single antiepileptic.
Minimum effective doses should be given and plasma levels monitored.
If woman receiving TEGRETOL becomes pregnant, or if the problem of initiating TEGRETOL arises during pregnancy, weigh the drug's potential benefits against its hazards, particularly during the first 3 months of pregnancy. Do not discontinue TEGRETOL or withhold from patients if required to prevent major seizures because of the risks posed, to both mother and fetus, by status epilepticus with attendant hypoxia.
Possibility that carbamazepine, like all major antiepileptic drugs, increases the risk of malformations has been reported. Rare reports on developmental disorders and malformations, including spina bifida, in association with carbamazepine. Conclusive evidence from controlled studies with carbamazepine monotherapy is lacking.
Folic acid deficiency is known to occur in pregnancy. Antiepileptic drugs have been reported to aggravate folic acid deficiency, which may contribute to increased incidence of birth defects in offspring of treated epileptic women. Folic acid supplementation is recommended before and during pregnancy.
Vitamin K_1 administration to mother during last weeks of pregnancy, and to newborn, has been recommended to prevent neonatal bleeding disorders.
Carbamazepine passes into breast milk in concentrations of about 25-60% of the plasma level. No reports available on long-term effect of breast feeding. Weigh benefits of breast feeding against possible risks to infant. Observe infant for possible adverse reactions, e.g., somnolence, should mother taking carbamazepine nurse.
A severe hypersensitivity skin reaction in a breast-fed baby has been reported.
Reliability of oral contraceptives may be adversely affected by carbamazepine (see **PRECAUTIONS, Drug Interactions**).

PRECAUTIONS Clinical Monitoring of Adverse Reactions: Prescribe TEGRETOL only after a critical risk-benefit appraisal in patients with a history of cardiac, hepatic or renal damage, adverse haematological reactions to other drugs, or interrupted courses of therapy with TEGRETOL. **Maintain careful clinical and laboratory supervision throughout treatment.** Should any signs or symptoms or abnormal laboratory findings be suggestive of blood dyscrasia or liver disorder, discontinue TEGRETOL immediately until case is carefully reassessed.
(a) **Bone marrow function:** Carry out complete blood counts, including platelets and possibly reticulocytes and serum iron, before treatment is instituted. Suggested guidelines for monitoring are weekly for the first month, monthly for the next 5 months, thereafter 2-4 times/year.
If definitely low or decreased white blood cell or platelet counts are observed during treatment, patient and complete blood count should be monitored closely. Non-progressive fluctuating asymptomatic leucopenia encountered, does not generally call for TEGRETOL withdrawal. However, treatment should be discontinued if the patient develops leucopenia which is progressive or accompanied by clinical manifestations, e.g. fever or sore throat, which could indicate onset of significant bone marrow depression.
Because onset of potentially serious blood dyscrasias may be rapid, patients should be made aware of early toxic signs and symptoms of potential hematological problem, and symptoms of dermatological or hepatic reactions. If reactions, e.g. fever, sore throat, rash, ulcers in mouth, easy bruising, petechial or purpuric hemorrhage appear, advise patient to consult his/her physician immediately.
(b) **Hepatic function:** Baseline and periodic evaluations of hepatic function must be performed, particularly in elderly patients and those with history of liver disease. Withdraw TEGRETOL immediately in cases of aggravated liver dysfunction or active liver disease.
(c) **Kidney function:** Perform pretreatment and periodic complete urinalysis and BUN determinations.
(d) **Ophthalmic examinations:** Carbamazepine has been associated with pathological eye changes. Periodic eye examinations, including slit-lamp funduscopy and tonometry recommended.
(e) **Plasma levels:** Although correlations between dosage and plasma levels, and between plasma levels and clinical efficacy or tolerability are rather tenuous, monitoring plasma levels may be useful in the following conditions: dramatic increase in seizure frequency/verification of patient compliance; pregnancy; when treating children or adolescents; suspected absorption disorders; suspected toxicity, especially where more than one drug is used (see "Interactions").
Increased Seizure Frequency: Use TEGRETOL with caution in patients with mixed seizure disorder that includes atypical absence seizures, since use has been associated with increased frequency of generalized convulsions. In case of exacerbation of seizures, discontinue TEGRETOL.
Dermatologic: Mild skin reactions, e.g., isolated macular or maculopapular exanthema, usually disappear within a few days or weeks, either during continued course of treatment or following dosage decrease. However, patient should be kept under close surveillance because of rare possibility of Steven-Johnson syndrome or Lyell's syndrome occurring (see WARNINGS).
Urinary Retention and Increased Intraocular Pressure: Because of its anticholinergic action, carbamazepine should be given cautiously, if at all, to patients with increased intraocular pressure or urinary retention. Follow such patients closely while on the drug.
Occurrence of Behavioural Disorders: Because it is closely related to other tricyclic drugs, there is a possibility that carbamazepine might activate latent psychosis, or, in elderly patients, produce agitation or confusion, especially when combined with other drugs. Exercise caution in alcoholics.
Use in Patients with Cardiovascular Disorders: Use TEGRETOL cautiously in patients with history of coronary artery disease, organic heart disease, or congestive failure. If defective conductive system suspected, perform an ECG before administering TEGRETOL, to exclude patients with atrioventricular block.
Driving and Operating Hazardous Machinery: Because dizziness and drowsiness are possible side effects of TEGRETOL, warn patients about possible hazards of operating machinery or driving automobiles.
Drug Interactions: Induction of hepatic enzymes in response to carbamazepine may diminish or abolish activity of certain drugs also metabolized in the liver. Dosage of the following drugs may have to be adjusted: clobazam, clonazepam, ethosuximide, primidone, valproic acid, alprazolam, corticosteroids (e.g. prednisolone, dexamethasone), cyclosporin, digoxin, doxycycline, felodipine, haloperidol, thioridazine, imipramine, methadone, oral contraceptives, theophylline, and oral anticoagulants (warfarin, phenprocoumon, dicumarol).
Phenytoin plasma levels reported to be both raised and lowered by carbamazepine, and mephenytoin plasma levels reported to increase in rare instances.
The following drugs have been shown to raise plasma carbamazepine levels: erythromycin, troleandomycin, possibly josamycin, isoniazid, verapamil, diltiazem, propoxyphene, viloxazine, fluoxetine, cimetidine, acetazolamide, danazol, and possibly desipramine. Nicotinamide raises carbamazepine plasma levels in children, but only at high dosage in adults. Since an increase in carbamazepine plasma levels may result in unwanted effects (e.g. dizziness, drowsiness, ataxia, diplopia and nystagmus), adjust TEGRETOL dosage accordingly and monitor the blood levels.
Plasma levels of carbamazepine may be reduced by phenobarbitone, phenytoin, primidone, progabide, or theophylline, and possibly by clonazepam. Alternatively, valproic acid, valpromide, and primidone have been reported to raise plasma levels of pharmacologically active metabolite, carbamazepine-10, 11 epoxide. TEGRETOL dose may consequently require adjustment.
Combined use with lithium, metoclopramide, or haloperidol, may increase risk of neurotoxic side effects (even in presence of "therapeutic plasma levels").
Concomitant use with isoniazid reported to increase isoniazid-induced hepatotoxicity.
TEGRETOL, like other anticonvulsants, may adversely affect the reliability of oral contraceptives; breakthrough bleeding may occur. Patients should accordingly be advised to use some alternative, non-hormonal method of contraception.
Concomitant medication with TEGRETOL and some diuretics (hydrochlorothiazide, furosemide) may lead to symptomatic hyponatremia.
TEGRETOL may antagonize effects of non-depolarising muscle relaxants (e.g. pancuronium); their dosage may need to be raised and patients should be monitored closely for more rapid recovery from neuromuscular blockade than expected.
Isotretinoin reported to alter the bioavailability and/or clearance of carbamazepine and its active 10, 11-epoxide; carbamazepine plasma levels should be monitored.
Carbamazepine, may reduce tolerance to alcohol; advisable to abstain from alcohol consumption during treatment.
TEGRETOL should not be administered in conjunction with MAO inhibitor. (See CONTRAINDICATIONS).

ADVERSE REACTIONS Reactions most frequently reported are CNS (e.g. drowsiness, headache, unsteadiness on feet, diplopia, dizziness), gastrointestinal disturbances (nausea, vomiting), and allergic skin reactions. These reactions usually occur only during the initial phase of therapy, if initial dose is too high, or when treating elderly patients. They have rarely necessitated discontinuing TEGRETOL therapy, and can be minimized by initiating treatment at low dosage.
Occurrence of CNS adverse reactions may be manifestation of relative overdosage or significant fluctuation in plasma levels. In such cases it is advisable to monitor plasma levels and possibly lower daily dose and/or divide it into 3-4 fractional doses.
More serious adverse reactions observed are hematologic, hepatic, cardiovascular and dermatologic reactions, which require discontinuation of therapy. If treatment is to be withdrawn abruptly, effect the change-over to another antiepileptic under cover of diazepam.
Adverse reactions reported:
Hematologic: Occasional or frequent – leucopenia; occasional – eosinophilia, thrombocytopenia; rare – leucocytosis, lymphadenopathy; isolated cases – agranulocytosis, aplastic anemia, pure red cell aplasia, macrocytic anemia, acute intermittent porphyria, reticulocytosis, folic acid deficiency, thrombocytopenic purpura, and possibly hemolytic anemia. In few instances, deaths occurred.
Hepatic: Frequent – elevated gamma-GT (due to hepatic enzyme induction), usually not clinically relevant; occasional – elevated alkaline phosphatase; rarely – transaminases; rare – jaundice, hepatitis of cholestatic, parenchymal, hepatocellular, or mixed type; isolated cases – granulomatous hepatitis.
Dermatologic: Occasional to frequent – skin sensitivity reactions and rashes, erythematous rashes, urticaria; rare – exfoliative dermatitis and erythroderma, Steven-Johnson syndrome, systemic lupus erythematosus-like syndrome; isolated cases – toxic epidermal necrolysis (Lyell's syndrome), photosensitivity, erythremia multiform and nodosum, skin pigmentation changes, pruritus, purpura, acne, diaphoresis, alopecia and neurodermatitis.
Neurologic: Frequent – vertigo, somnolence, ataxia and fatigue. Occasionally – an increase in motor seizures (see INDICATIONS), headache, diplopia, nystagmus, accommodation disorders (e.g. blurred vision); rare – abnormal involuntary disorders (e.g. tremor, asterixis, orofacial dyskinesia, choreoathetosis disorders, dystonia, tics); isolated cases – oculomotor disturbances, speech disorders (e.g. dysarthria or slurred speech), peripheral neuritis, paraesthesiae. There have been some reports of paralysis and other symptoms of cerebral arterial insufficiency but no conclusive relationship to the administration of TEGRETOL could be established.
Cardiovascular: Disturbances of cardiac conduction, bradycardia, arrhythmias, Stokes-Adams in patients with AV-block, congestive heart failure, hypertension or hypotension, aggravation of coronary artery disease, thrombophlebitis, thromboembolism. Some of these complications (including myocardial infarction and arrhythmia) have been associated with other tricyclic compounds.
Psychiatric: Isolated cases – hallucinations (visual or acoustic), depression, sometimes with talkativeness, agitation, loss of appetite, restlessness, aggressive behaviour, confusion, activation of psychosis.

Genitourinary: Isolated cases – interstitial nephritis and renal failure, as well as signs of renal dysfunction (e.g. albuminuria, glycosuria, hematuria, oliguria sometimes associated with elevated blood pressure, and elevated BUN/azotemia), urinary frequency, urinary retention, and renal failure.
Isolated reports – sexual disturbances/impotence.
Gastrointestinal: Occasional or frequent – nausea, vomiting. Occasional: dryness of the mouth and throat; rare – diarrhoea or constipation; isolated cases – abdominal pain, glossitis, stomatitis, anorexia.
Sense Organs: Isolated cases – lens opacities, conjunctivitis, retinal changes, tinnitus, hyperacusis, and taste disturbances.
Endocrine System and Metabolism: Occasionally edema, fluid retention, weight increase, hyponatremia and reduced plasma osmolality due to antidiuretic hormone (ADH)-like effect, leading in isolated cases to water intoxication accompanied by lethargy, vomiting, headache, mental confusion, neurological abnormalities. Isolated cases of gynecomastia or galactorrhea have been reported, as well as abnormal thyroid function tests (decreased L-thyroxine, i.e., FT_4, T_4, T_3, and increased TSH, usually without clinical manifestations), disturbances of bone metabolism (decrease in plasma calcium and 25-OH-calciferol), leading in isolated cases to osteomalacia, as well as reports of elevated levels of cholesterol, including HDL cholesterol and triglycerides.
Musculoskeletal System: Isolated cases – arthralgia, muscle pain or cramp.
Respiratory: Isolated cases – pulmonary hypersensitivity characterized by fever, dyspnea, pneumonitis or pneumonia.
Hypersensitivity reactions: Rare delayed multi-organ hypersensitivity disorder with fever, skin rashes, vasculitis, lymphadenopathy, disorders mimicking lymphoma, arthralgia, leucopenia, eosinophilia, hepato-splenomegaly and abnormal liver function tests, occurring in various combinations. Other organs may also be affected (e.g. lungs, kidneys, pancreas, myocardium).
Isolated cases: aseptic meningitis, with myoclonus and eosinophilia; anaphylactic reaction. Treatment should be discontinued should such hypersensitivity reactions occur.
SYMPTOMS AND TREATMENT OF OVERDOSAGE Lowest Known Lethal Dose: estimated 3.2g (24 year old woman). Highest known doses survived: 80g (34 year old man); 34g (13 year old girl); 1.4g (23 month old girl).
Symptoms of Overdosage: The presenting signs and symptoms of overdosage usually involve the central nervous, cardiovascular, and respiratory systems.
Central Nervous System: CNS depression, disorientation, tremor, restlessness, somnolence, agitation, hallucination, coma, blurred vision, nystagmus, mydriasis, slurred speech, dysarthria, ataxia, dyskinesia, abnormal reflexes (slow/hyperactive), convulsions, psychomotor disturbances, myoclonus, opisthotonia, hypothermia/hyperthermia, flushed skin/cyanosis, EEG changes.
Respiratory System: Respiratory depression, pulmonary edema.
Cardiovascular System: Tachycardia, hypotension/hypertension, conduction disturbance with widening of QRS complex, syncope in association with cardiac arrest.
Gastrointestinal System: Nausea, vomiting, delayed gastric emptying, reduced bowel motility.
Renal Function: Urinary retention, oliguria or anuria; fluid retention, and water intoxication.
Laboratory Findings: Hyponatremia, hypokalemia, leukocytosis, reduced white cell count, metabolic acidosis, hyperglycemia, glycosuria, acetonuria, increased muscle creatinine phosphokinase.
Treatment of Overdosage: There is no known specific antidote to TEGRETOL (carbamazepine).
Evacuate the stomach, with an emetic or by gastric lavage, then administer activated charcoal.
Observe vital signs and administer symptomatic treatment as required. Hyperirritability or convulsions may be controlled by the administration of parenteral diazepam or barbiturates but they may induce respiratory depression, particularly in children. Paraldehyde may be used to counteract muscular hypertonus without producing respiratory depression.
When barbiturates are employed, it is advisable to have equipment available for artificial ventilation and resuscitation.
Barbiturates should not be used if drugs that inhibit monoamine oxidase have been taken by the patient, either in overdosage or in recent therapy (within two weeks).
Hyponatremia should be treated by restricting fluids and a slow and careful NaCl 0.9% infusion i.v. These measures may be useful in preventing brain damage.
Shock (circulatory collapse) should be treated with supportive measures, including intravenous fluids, oxygen, and corticosteroids. For hypotension unresponsive to measures taken to increase plasma volume, dopamine or dobutamine i.v. may be administered.
It is recommended that ECG be monitored, particularly in children, to detect cardiac arrhythmias or conduction defects.
Charcoal hemoperfusion has been recommended. Forced diuresis, hemodialysis, and peritoneal dialysis reported to be ineffective.
Relapse and aggravation of the symptomatology on the 2nd or 3rd day after overdose, due to delayed absorption, should be anticipated.
DOSAGE AND ADMINISTRATION Use in Epilepsy (See INDICATIONS): Low initial daily dosage of TEGRETOL (carbamazepine) with a gradual increase in dosage is advised. Adjust dosage to the needs of the individual patient.
TEGRETOL tablets and CHEWTABS should be taken in 2 to 4 divided doses daily, with meals when possible.
Controlled release characteristics of TEGRETOL CR reduce the daily fluctuations of plasma carbamazepine. TEGRETOL CR tablets (either whole or, if so prescribed, half a tablet) should be swallowed unchewed with a little liquid during or after a meal. Controlled release tablets should be prescribed as a b.i.d. dosage. If necessary, 3 divided doses may be prescribed.
Adults and Children Over 12 Years: Initially, 100 to 200 mg once or twice a day depending on the severity of the case and previous therapeutic history. Initial dosage is progressively increased, in divided doses, until best response is obtained. Usual optimal dosage is 800 to 1200 mg daily. In rare instances some adult patients have received 1600 mg. As soon as disappearance of seizures has been obtained and maintained, reduce dosage very gradually until reaching minimum effective dose.
Children 6-12 Years: Initially, 100 mg in divided doses on first day. Increase gradually by adding 100 mg/day until best response is obtained. Dosage should generally not exceed 1000 mg daily. As soon as disappearance of seizures has been obtained and maintained, reduce dosage very gradually until reaching minimum effective dose.
Use in Trigeminal Neuralgia: Initial daily dosage 200 mg taken in 2 doses of 100 mg is recommended. Total daily dosage can be increased by 200 mg/day until relief of pain is obtained, usually achieved at dosage 200-800 mg daily; occasionally up to 1200 mg/day necessary. As soon as relief of pain has been obtained and maintained, attempt progressive reduction in dosage until reaching minimal effective dosage. Because trigeminal neuralgia is characterized by periods of remission, attempts should be made to reduce or discontinue the use of TEGRETOL at intervals of not more than 3 months, depending on individual clinical course.
Prophylactic use in trigeminal neuralgia is not recommended.
Use in Mania and Bipolar (Manic Depressive) Disorders: Low initial dosage of 200-400 mg/day, in divided doses, higher starting doses of 400-600 mg/day may be used in acute mania. May be gradually increased until symptomatology is controlled or a total daily dose of 1600 mg. Adjust dosage increments for optimal tolerability. Usual dose is 400-1200 mg/day in divided doses. For maintenance, continue with doses used to achieve optimal acute responses and tolerability. In combination with lithium, neuroleptics: initially a low dosage of 100-200 mg/day; gradually increase. Daily dose > 800 mg is rarely required when given in combination with neuroleptics, lithium or other psychotropics, e.g., benzodiazepines. Plasma levels are probably not helpful for guidance in bipolar disorders.
AVAILABILITY TEGRETOL Tablets 200 mg: Each white, round, flat, bevelled-edge double-scored tablet engraved GEIGY on one side contains 200 mg carbamazepine. Protect from heat (store below 30°C) and humidity. Bottles of 100/500. **TEGRETOL CHEWTABS 100 mg:** Pale pink, round, flat, bevelled-edge tablets with distinct red spots. GEIGY engraved on one side and MR on the other. Fully bisected between the M and R. Each contains 100 mg carbamazepine. Protect from heat (store below 30°C), light and humidity. Bottles of 100. **TEGRETOL CHEWTABS 200 mg:** Pale pink, oval, biconvex tablets with distinct red spots. GEIGY engraved on one side and PU engraved on the other. Fully bisected between the P and U. Each contains 200 mg carbamazepine. Protect from heat (store below 30°C), light and humidity. Bottles of 100. **TEGRETOL CR 200 mg:** Beige-orange, oval, slightly biconvex tablet, engraved CG on one side and HC on the other. Fully bisected on both sides. Each contains 200 mg carbamazepine. Protect from heat (store below 25°C) and humidity. Bottles of 100. **TEGRETOL CR 400 mg:** Brownish-orange, oval, slightly biconvex tablet, engraved CG/CG on one side and ENE/ENE on the other. Fully bisected on both sides. Each contains 400 mg carbamazepine. Protect from heat (store below 25°C) and humidity. Bottles of 100. TEGRETOL is available to patients only by prescription.
Product Monograph available on request. January 4, 1993

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There are ways of telling when a young epilepsy patient is on Tegretol® CR.

Excellent Seizure Control.

Tegretol CR (controlled-release carbamazepine) controls seizures in many patients–with little impact on cognitive function.[1,2,3,4] Unlike drugs such as phenytoin, Tegretol CR can leave many patients free to think clearly and do their best.[1,2,3,4]

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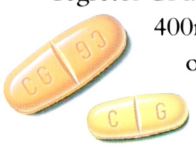
When initiating or switching therapy, consider Tegretol CR. It comes in easy-to-break 200mg and 400mg tablets for dosage flexibility, and offers B.I.D. dosing to enhance patient compliance.



TEGRETOL® CR.

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