Intermediate Prescribing Information

℞ Tegretol® (carbamazepine)

TEGRETOL® 200 mg
TEGRETOL® CHEWTABS™ 100 mg and 200 mg
TEGRETOL® CR 200 mg and 400 mg

Indications

Symptomatic relief of pain of true or primary trigeminal neuralgia. Not for prophylactic use. Glossopharyngeal neuralgia has been relieved in some patients.

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.

Contraindications

History of hepatic disease or serious blood disorder, in patients with AV heart block *(see Precautions)*, hypersensitivity to carbamazepine or to tricyclic compounds.

Do not give with, or within 2 weeks of treatment with monoamine oxidase inhibitors.

Safe use in pregnancy has not been established. Do not administer in first 3 months of pregnancy. Do not give to women of childbearing potential unless benefits outweigh possible risks to the fetus. Avoid nursing while on TEGRETOL.

Warnings

Although infrequent, serious adverse effects have occurred during TEGRETOL use. Agranulocytosis and aplastic anemia have occurred in a few instances with fatal outcome. Leucopenia, thrombocytopenia, hepatocellular and cholestatic jaundice, and hepatitis have occurred. Use TEGRETOL carefully with close clinical and laboratory supervision during treatment in order to detect signs and symptoms of blood dyscrasias.

Long-term toxicity studies in rats showed potential carcinogenic risk. Weigh possible risk of drug use against potential benefits before prescribing carbamazepine.

Precautions

Perform complete blood studies, including platelet counts, and evaluate hepatic and renal function and urinalysis before starting treatment. Maintain close clinical and laboratory supervision during treatment, including frequent complete blood counts. Discontinue TEGRETOL if signs or symptoms or abnormal laboratory findings suggestive of blood dyscrasia or liver disorder occur until case is reassessed.

Non-progressive or fluctuating asymptomatic leucopenia may occur and does not generally require TEGRETOL withdrawal. Discontinue TEGRETOL if the patient develops leucopenia which is progressive or accompanied by clinical symptoms.

Give TEGRETOL cautiously, if at all, to patients with increased intraocular pressure or urinary retention. Monitor closely.

TEGRETOL may activate latent psychosis, or cause agitation or confusion, especially when used with other drugs. Use caution in alcoholic patients.

Use cautiously in patients with history of coronary artery disease, organic heart disease, or congestive failure. If a defective conductive system is suspected, perform an ECG to exclude patients with AV block.

Warn patients of possible hazards of operating machinery or driving automobiles due to possible dizziness and drowsiness with therapy.

Drug Interactions:

Hepatic enzyme induction by TEGRETOL may diminish activity of drugs metabolized in the liver.

Combined use of TEGRETOL with verapamil, diltiazem, erythromycin, troleandomycin, cimetidine, propoxyphene or isoniazid, can result in elevated plasma carbamazepine levels. Adapt carbamazepine dosage and monitor blood levels.

Concomitant use of carbamazepine and lithium may increase neurotoxic side effect risk.

Adapt dosage of anticoagulants to clinical needs whenever TEGRETOL is initiated or withdrawn.

TEGRETOL may decrease reliability of oral contraceptives. Advise patients to use alternative, non-hormonal method of contraception.

TEGRETOL may reduce alcohol tolerance; avoid alcohol during treatment.

Do not administer TEGRETOL in conjunction with MAO inhibitors. *(See Contraindications.)*

Adverse Reactions

Hematologic – Transitory leucopenia, eosinophilia, hyponatremia, leucocytosis, thrombocytopenic purpura, agranulocytosis, macrocytic anemia, aplastic anemia. In a few cases, deaths have occurred.

Hepatic – During long-term use, abnormal liver function tests, cholestatic and hepatocellular jaundice, hepatitis.

Dermatologic – Skin sensitivity reactions and rashes, erythematous rashes, pruritic eruptions, urticaria, photosensitivity, pigmentary changes, neurodermatitis. In rare cases Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis, alopecia, diaphoresis, erythema multiforme, erythema nodosum, aggravation of disseminated lupus erythematosus.

Neurologic – Vertigo, somnolence, ataxia, confusion, headache, fatigue, blurred vision, visual hallucinations, transient diplopia and oculomotor disturbances, speech disturbances, abnormal involuntary movements, increase in motor seizures. In rare cases, peripheral neuritis and paresthesia, depression with agitation, talkativeness, nystagmus, hyperacusis, and tinnitus. There have been reports of paralysis and other symptoms of cerebral arterial insufficiency but no conclusive relationship to TEGRETOL could be established.

Cardiovascular – Thromboembolism, recurrence of thrombophlebitis in patients with prior history of thrombophlebitis, primary thrombophlebitis, congestive heart failure, aggravation of hypertension, Stokes-Adams in patients with AV block, hypotension, syncope and collapse, edema, aggravation of coronary artery disease. Some of these effects (including myocardial infarction and arrhythmia) have been associated with other tricyclic agents.

Genitourinary – Urinary frequency, acute urinary retention, oliguria with elevated BP, azotemia, renal failure, impotence, elevation of BUN, albuminuria, glycosuria.

Respiratory – Pulmonary hypersensitivity characterized by fever, dyspnea, pneumonitis or pneumonia.

Gastrointestinal – Nausea, vomiting, gastric or abdominal discomfort, diarrhea or constipation, anorexia, dryness of the mouth and throat, glossitis, stomatitis.

Ophthalmic – There is no conclusive evidence that TEGRETOL produces pathological changes in the cornea, lens or retina. However, many phenothiazines and related drugs have been shown to cause eye changes. Periodic eye examinations, including slit-lamp fundoscopy and tonometry, are recommended.

Other: fever and chills, aching joints and muscles, leg cramps, conjunctivitis, adenopathy or lymphadenopathy.

Dosage and Administration

Epilepsy:

Take TEGRETOL tablets and CHEWTABS in 2-4 divided doses daily, with meals whenever possible.

Swallow TEGRETOL CR tablets (either whole or, if so prescribed, only half a tablet) unchewed with some liquid during or after meals. These should be prescribed as a twice-daily dosage. If needed, 3 divided doses may be prescribed.

Adults and Children Over 12 Years of Age:

Initially, 100-200 mg 1-2 times/day depending on severity of case and previous therapeutic history. Increase dose progressively, in divided doses, until best response obtained. Usual optimal dosage is 800-1200 mg/day. Rarely, some adults have received 1600 mg. Once seizures disappear and remain controlled, reduce dose very gradually until minimum effective dose is reached.

Children 6-12 Years of Age:

Initially, 100 mg in divided doses on Day 1. Increase gradually by 100 mg/day until best response is obtained. Do not exceed 1000 mg/day. Once seizures disappear and remain controlled, reduce dose very gradually until minimum effective dose is reached.

Trigeminal Neuralgia:

Initially, 200 mg in 2 doses of 100 mg. Increase total daily dosage by 200 mg/day until pain relief is obtained. This usually occurs at 200-800 mg/day, but 1200 mg/day may be needed. Reduce dose progressively once pain relief is obtained and maintained, until minimal effective dosage is reached. Because trigeminal neuralgia is characterized by periods of remission, attempt to reduce or discontinue TEGRETOL at intervals of not more than 3 months, depending upon clinical course.

Not for prophylactic use.

Availability

TEGRETOL Tablets 200 mg: Each white, round, flat, bevelled-edge double-scored tablet engraved GEIGY on one side contains 200 mg carbamazepine. Bottles of 100 and 500 tablets.

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 chewable tablet contains 100 mg carbamazepine. Bottles of 100 CHEWTABS.

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 chewable tablet contains 200 mg carbamazepine. Bottles of 100 CHEWTABS.

TEGRETOL CR 200 mg: Beige-orange, capsule-shaped, slightly biconvex tablet, engraved CG/CG on one side and HC/HC on the other. Fully bisected on both sides. Each controlled release tablet contains 200 mg carbamazepine. Bottles of 100 tablets.

TEGRETOL CR 400 mg: Brownish-orange, capsule-shaped, slightly biconvex tablet, engraved CG/CG on one side and ENE/ENE on the other. Fully bisected on both sides. Each controlled release tablet contains 400 mg carbamazepine. Bottles of 100 tablets.

Protect from heat and humidity.

Product Monograph available on request.

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