

CARBATOL

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

Abbreviated Prescribing information for CARBATOL (Carbamazepine 100mg and 200mg Tablet)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: In controlled clinical trials, carbamazepine has been shown to be effective in the treatment of psychomotor and grand mal seizures, as well as trigeminal neuralgia. **INDICATION:** Partial seizures with complex symptomatology generalized tonic-clonic seizures (grand mal), mixed seizure patterns which include the above, or other partial or generalized seizures, pain associated with true trigeminal neuralgia and glossopharyngeal neuralgia. **DOSAGE AND ADMINISTRATION: For Epilepsy: Adults:** Initially 100- 200mg once or twice daily, slow increase to 800-1200mg daily until the best response is obtained. In some instances, 1600mg or even 2000mg daily may be necessary. **Elderly:** Exercise caution due to the potential for drug interactions. **Children:** 10-20mg/kg bodyweight daily taken in divided doses. 1-5 years: 2-4 x 100mg tablets per day, where appropriate, for 5-10 years: 2-3 x 200mg tablets per day, to be taken in divided doses, for 10-15 years: 3-5 x 200mg tablets per day, to be taken in several divided doses. Not recommended for very young children. **Trigeminal neuralgia:** Initial dosage of 200-400mg daily (100mg twice daily in elderly patients). Slowly raise the dose till 200mg 3-4 times a day. In some instances, doses of 1600mg carbamazepine daily may be needed. **CONTRAINDICATION:** History with bone marrow depression, hypersensitivity to the drug, or known sensitivity to any of the tricyclic compounds. Concomitant use with monoamine oxidase inhibitors (discontinued for a minimum of 14 days, or longer if the clinical situation permits) and nefazodone. **WARNINGS & PRECAUTIONS:** Toxic epidermal necrolysis (TEN) and Stevens-Johnson syndrome (SJS), aplastic anemia and agranulocytosis, drug reaction with eosinophilia and systemic symptoms (DRESS), suicidal behavior and ideation, hepatic porphyria, condition with increased intraocular pressure, fetal harm in pregnant woman, Exercise caution while use in patients with mixed seizure disorder that includes atypical absence seizures, second and third degree AV heart block, high-resolution 'HLA-B*1502 test required for genetically at risk patient, hyponatremia, decreased values of thyroid function test. **DRUG INTERACTIONS:** With CYP3A4 inhibitors and inducers, drugs metabolized by CYP3A4, lithium, isoniazid, diuretics (hydrochlorothiazide, furosemide), hormonal contraceptive products (e.g., oral, and levonorgestrel subdermal implant contraceptives) and nondepolarizing neuromuscular blocking agents. **ADVERSE REACTIONS:** Dizziness, drowsiness, unsteadiness, nausea, and vomiting, bone marrow depression, acute generalized exanthematous pustulosis (AGEP), photosensitivity reactions, alterations in skin pigmentation, exfoliative dermatitis, erythema multiforme and nodosum, alopecia, diaphoresis and onychomadesis, congestive heart failure, aggravation of hypertension, hypotension, aggravation of coronary artery disease, arrhythmias, thrombophlebitis, thromboembolism, adenopathy, myocardial infarction, cholestatic and hepatocellular jaundice, hepatitis, pancreatitis, pulmonary hypersensitivity, urinary frequency, acute urinary retention, oliguria with elevated blood pressure, azotemia, renal failure, impotence, albuminuria, glycosuria, elevated BUN, microscopic deposits, disturbances of coordination, blurred vision, visual hallucinations, transient diplopia, oculomotor disturbances, nystagmus, speech disturbances, abnormal involuntary movements, peripheral neuritis and paresthesias, depression with agitation, tinnitus, hyperacusis, neuroleptic malignant syndrome, paralysis, cerebral arterial insufficiency, gastric distress and abdominal pain, diarrhea, constipation, anorexia, dryness of the mouth and pharynx, including glossitis and stomatitis, scattered punctate cortical lens opacities, aching joints and muscles, and leg cramps, inappropriate antidiuretic hormone (ADH) secretion syndrome, lupus erythematosus-like syndrome and aseptic meningitis.

MARKETED BY:



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IN/ CARBATOL 100,200mg/ Jul-15/01/AbPI
(Additional information is available on request)