CARBATOL CR

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

Abbreviated Prescribing information for CARBATOL CR **(**Carbamazepine Extended release Tablets 200mg, 300mg, 400mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

An antiepileptic agent with spectrum of activity: Partial seizures (simple and complex) with and without secondary generalisation; generalised tonic-clonic seizures, as well as combinations of these types of seizures. **INDICATION:** For epilepsy including generalised tonic-clonic and partial seizures, paroxysmal pain of trigeminal neuralgia and for the prophylaxis of manic-depressive psychoses in patients unresponsive to lithium therapy. **DOSAGE AND ADMINISTRATION: Epilepsy:** 100-200mg once or twice daily is recommended for starting the therapy which may be followed by a slow increase in dosage until the best response is obtained, often 800-1200mg daily. In some instances, 1600mg or even 2000mg daily may be necessary. Tablets should not be chewed but should be swallowed with a little liquid, before, during or between meals. Children: 10-20mg/kg bodyweight daily taken in divided doses. Age up to 5 years not recommended. 5-10 years: 400-600mg daily, 10-15 years: 600-1000 mg. **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. **For the prophylaxis of manic depressive psychosis in patients unresponsive to lithium therapy:** Initial starting dose of 400mg daily, in divided doses, increasing gradually until symptoms are controlled or a total of 1600mg given in divided doses is reached. The usual dosage range is 400-600mg daily, given in divided doses. **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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(Additional information is available on request)