xxxxxxxx-8883

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

CARBATOL CR

(Carbamazepine Controlled Release Tablets, 200mg and 400mg)

Carbamazepine, an anticonvulsant is an iminostilbene derivative chemically related to the tricyclic antidepressants.

CLINICAL PHARMACOLOGY

Mechanism of action

Mechanism of action of carbamazepine is unknown but it appears to act by inhibiting the spread at the polysynaptic pathways and blocking the post-tetanic potentiation.

Pharmacokinetics

It is adequately absorbed, with peak serum levels achieved within 4-5 hours. Transplacental passage of carbamazepine is rapid. Carbamazepine is metabolized in liver to 10, 11-epoxide, which also has anticonvulsant activity. It may induce its own metabolism. Initial half-life ranges from 25-65 hours, and decreases to 12-17 hours with repeated doses. The half-life of the metabolite is 5-8 hours. 72% of a dose is found in urine and 28% in faeces.

INDICATIONS

Refractory seizure disorders – Carbatol CR is indicated in partial seizures with complex symptoms (psychomotor, temporal lobe). Patients with these seizures appear to show greatest improvement. Generalized tonic - clonic seizures (grandmal); Mixed seizure patterns or other partial or generalized seizures.

Trigeminal neuralgia - Treatment of pain associated with trigeminal neuralgia. Beneficial results have also been reported in glossopharyngeal neuralgia.

Unlabelled uses - Carbatol CR has been used to treat neurogenic diabetes insipidus. It has demonstrated efficacy in certain psychiatric disorders, including bipolar disorders, schizoaffective illness, resistant schizophrenia and dyscontrol syndrome in children associated with limbic system dysfunction. Carbatol CR has also been employed in the management of alcohol withdrawal syndrome, Hemifacial spasm & Diabetic neuropathy.

CONTRAINDICATIONS

History of bone marrow depression; hypersensitivity to carbamazepine and tricyclic antidepressants; concomitant use of MAO inhibitors.

PRECAUTIONS

Restrict treatment of epilepsy to those classifications listed under indications. Discontinue, if a patient exhibits evidence of marrow suppression. Use with caution in patients with increased intraocular pressure. Discontinue MAO inhibitors for a minimum of 14 days before Carbatol CR administration. Patients should observe caution while driving or performing other tasks requiring alertness, as it may produce drowsiness, dizziness. Prescribe Carbatol CR, only after benefit-risk appraisal is done in patients with a history of cardiac, hepatic or renal damage. Perform baseline liver function tests at regular intervals. Safety for use during pregnancy, lactation and in children below 6 years has not been established.

ADVERSE REACTIONS

Dizziness, drowsiness, unsteadiness, nausea and vomiting are reported frequently. Less frequently aplastic anemia, leukopenia, agranulocytosis, eosinophilia, leukocytosis thrombocytopenia, abnormal liver function tests, have been reported in some patients.

Potentially hazardous tasks - May produce drowsiness, dizziness or blurred vision; patients should observe caution while driving or performing other tasks requiring alertness.

Special risk patients - Prescribe Carbatol CR only after benefit-to-risk appraisal in patients with a history of: Cardiac, hepatic or renal damage; adverse hematological reaction to other drugs; interrupted course of therapy with the drug.

Laboratory Tests - Perform baseline liver function tests at regular intervals. Discontinue drug immediately if liver dysfunction occurs. Obtain baseline and periodic eye examinations (slit lamp, fundoscopy and tonometry), urinalysis and BUN determinations. The monitoring of blood levels may be particularly useful in cases of dramatic increase in seizure frequency, for verification of compliance and in determining the cause of toxicity when more than one medication is being used.

DOSAGE AND ADMINISTRATION

Carbatol CR tablets must be swallowed whole and never be crushed or chewed.

Individualize dosage - A low initial daily dosage with gradual increase is advised. As soon as adequate control is achieved, reduce dosage gradually to the minimum effective level. Take with meals.

Epilepsy: Adults and Children (over 12 years): Initially 200mg twice daily. Increase at weekly intervals by 200mg in divided dosage regimen until best response is obtained. Do not exceed 1000mg/day in children 12-15 years or 1200 mg/day in patients over 15 years. In rare instances, doses upto 1600mg/day have been used in adults.

Maintenance: usually 800-1200mg daily.

Children (6-12 years) : 20-30 mg/kg/day, in divided doses 3-4 times a day. Maintenance: Usually 400-800mg daily.

Trigeminal neuralgia: Initial: 100mg twice daily on the first day. May increase by 200mg/day using 100mg increments every 12 hours as needed. Do not exceed 1200 mg daily. Maintenance: 400- 800mg daily.

Prophylaxis of manic-depressive psychosis: Initially 400mg daily in divided doses, increasing gradually until symptoms are controlled or total 1600mg daily dose, is reached. Usual range 400-600mg in divided dosage.

DRUG INTERACTIONS

Troleandomycin and erythromycin may increase serum levels of carbamazepine causing manifestations of toxicity. Breakthrough bleeding has been reported in women receiving concomitant oral contraceptives; the reliability of oral contraceptives may be adversely affected.

The simultaneous administration of phenobarbital, phenytoin or primidone, or a combination, may lower serum levels of carbamazepine. No loss of seizure control has been reported with the addition of phenobarbital or phenytoin, since the anticonvulsant action is probably additive with carbamazepine. In addition, studies indicate that the half life of active metabolite of primidone i.e phenobarbital may be increased by carbamazepine.

The half life of doxycycline was reduced when administered with Carbamazepine. Cimetidine, isoniazid and propoxyphene may inhibit the metabolism of Carbamazepine. Elevated carbamazepine concentrations may result in CNS toxicity. Conversely, Carbamazepine may increase the risk of isoniazid-induced hepatotoxicity. Carbamazepine may potentiate the antidiuretic effects of vasopressin, lypressin or desmopressin.

Charcoal may decrease the GI absorption of Carbamazepine. The pharmacologic effects of theophylline may be decreased by carbamazepine.

Drug/Lab Tests - Thyroid function tests show decreased values with Carbamazepine. Thyroid function alterations have occurred in combination with other anticonvulsants.

OVERDOSAGE

Symptoms include neuromuscular disturbances, cardiovascular complications, irregular breathing, respiratory depression, impaired consciousness ranging to deep coma, convulsions, especially in small children, motor restlessness, muscular twitching, and tremors. Irrigate stomach repeatedly. There is no specific antidote. Replacement transfusion is indicated in severe poisoning in small children.

STORAGE

Store below 30°C, protected from moisture

PRESENTATION

Carbatol CR-200: It is available in the strips of 10 tablets. Each tablet containing Carbamazepine B.P. 200mg.

Carbatol CR-400: It is available in the strips of 10 tablets. Each tablet containing Carbamazepine B.P. 400mg.

torrent PHARMA

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Baddi 173 205, Dist. Solan (H.P.) INDIA.

PRODUCT NAME	: Carbatol CR	**COUNTRY : Reg. Eng.**	**LOCATION :** Baddi		**Supersedes A/W No.:**		
ITEM / PACK	: Insert	**NO. OF COLOURS : 1**	**REMARK :**				
DESIGN STYLE	: -	**PANTONE SHADE NOS :**	**SUBSTRATE :**				
CODE	: xxxxxxxxxx-8883	Black	**Activities**	**Department**	**Name**	**Signature**	**Date**
DIMENSIONS (MM)	: 150 x 200		Prepared By	**Pkg. Dev**			
ART WORK SIZE	: S/S		Reviewed By	**Pkg. Dev**			
DATE	: 29-05-2014			**RA**			
			Approved By	**CQA**			