

CTD MODULE 1
ADMINISTRATIVE INFORMATION AND
PRODUCT INFORMATION

Product Name :	REZEPINE TABLETS (Carbamazepine 200mg)
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Pack Insert:

REZEPINE TABLETS

Carbamazepine Tablets BP 200mg

DESCRIPTION:

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

CLINICAL PHARMACOLOGY:

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. 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 the dose is found in urine and 28% in faeces.

INDICATIONS:

Partial seizures with complex symptoms (psychomotor, temporal lobe); Generalized tonic-clonic seizures (grand mal); Mixed seizure patterns or other partial or generalized seizures; pain associated with true trigeminal neuralgia; glossopharyngeal neuralgia; for prophylaxis of manic depressive psychosis in patients unresponsive to lithium therapy.

CONTRA INDICATIONS:

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 the 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 carbamazepine administration. Patients should observe caution while driving or performing other tasks requiring alertness, as it may produce drowsiness, dizziness. Prescribe Rezepine, 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 anaemia, leukopenia, agranulocytosis, eosinophilia, leukocytosis thrombocytopenia, abnormal liver function tests, have been reported in some patients.

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DRUG INTERACTIONS:

Erythromycin may increase serum levels of carbamazepine. Breakthrough bleeding has been reported in women receiving concomitant oral contraceptives. Simultaneous administration of phenobarbital, phenytoin or primidone, or combination, may lower serum levels of carbamazepine with no loss of the seizure control. Half-life of doxycycline was reduced when administered with carbamazepine. Cimetidine, isoniazid and propoxyphene may inhibit the metabolism of carbamazepine. Carbamazepine may potentiate the antidiuretic effects of vasopressin, or desmopressin.

DOSAGE AND ADMINISTRATION:

Epilepsy: Adults and children (over 12 years): Initially 100mg 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 1200mg/day in patients over 15 years. In rare instances, doses upto 1600 mg/day have been used in adults. Maintenance: usually 800- 1200mg daily.
Children (6-12 years): 20-30mg/kg/day, in divided doses 3-4 times a day.

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 1200mg 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 400-600 mg in divided dosage.

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. Dialysis is indicated only in severe poisoning associated with renal failure. Replacement transfusion is indicated in severe poisoning in small children.

STORAGE INSTRUCTION:

Store below 30°C.
Store in a cool dry place
Protect from light.

PRESENTATION:

Rezepine Tablets are available in Blister Pack of 10x 10's; each uncoated tablet contains 200mg of carbamazepine BP.

NOTE: For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

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