

# Epilep<sup>®</sup>

Tablet/CR Tablet

## Description

Epilep contains Carbamazepine which is an iminodibenzyl derivative with anticonvulsant properties and its structure is related to the tricyclic antidepressants. It is a white or yellowish white, crystalline, almost odourless powder which is tasteless or with a slightly bitter taste.

## Indications

Carbamazepine is indicated in all forms of epilepsy except myoclonic and absence seizures. It is also indicated in trigeminal neuralgia, mood disorder, aggression and diabetes insipidus.

## Dosage and Administration

*Epilepsy:*

Dosage in adults : 100-200 mg once or twice daily and this is then gradually increased by 200 mg daily every week. The best response is often obtained with doses of 800-1200 mg daily. In some instances 1600 mg or even 2000 mg daily may be necessary.

Dosage in children : The dose in children is determined on the basis of body weight (10-20 mg/kg) and age. Children up to 1 year of age : 100-300 mg daily in two to four divided doses. Children between 1 to 5 years of age : 200-400 mg daily in two to four divided doses. Children between 6 to 10 years of age : 400-600 mg daily in two to four divided doses. Children between 11 to 15 years of age : 600-1000 mg daily in two to four divided doses.

*Trigeminal neuralgia:* The initial dose is usually 200 mg daily. In some instances a dose of 1600 mg daily is necessary.

*Mood disorder:* In patients unresponsive to Lithium therapy, a starting dose of 400-600 mg daily is used.

*Diabetes insipidus:* 200 mg two to three times daily. In children the dose should be determined according to body weight (10-20 mg/kg).

## Precautions

Carbamazepine should be used with caution in cardiovascular disease, hepatic or renal disorders, changing treatment from Carbamazepine to another antiepileptic drug, haematological disorder, glaucoma etc.

## Contraindications

Previous sensitivity to Carbamazepine or structurally related drugs, atrioventricular conduction abnormalities, history of previous bone marrow depression or of intermittent porphyria.

## Drug Interactions

Drugs	Effects
Anticoagulants Oral contraceptive Propoxyphene	Reduced anticoagulant effect Increased contraceptive effect Interference with the metabolism and clearance of Carbamazepine
Fluvoamine MAO Inhibitors Anticonvulsants Alcohol	Provoked symptomatic Carbamazepine toxicity Increased incidence of cardiac arrhythmias Induction of hepatic microsomal enzyme CNS side effects of Carbamazepine possibly increased
Doxycycline Salicylic acid	Shorter half-life of Doxycycline Increased free Carbamazepine concentration in plasma
Vitamin D Lithium	Interference with the metabolism of Vitamin D Neurotoxic reactions have been occurred.

## Side Effects

Potentially Life Threatening	Severe or Irreversible	Symptomatic
Aplastic anaemia, Agranulocytosis, Fatal hepatitis, Severe exfoliative dermatitis, Toxic epidermal necrolysis, Stevens-Johnson syndrome, Lupus erythematosus	Generalised erythematous skin rashes, Transient leucopenia, Thrombocytopenia, Oliguria, Haematuria, Proteinuria, Renal failure, Bradycardia, Heart failure	Dizziness, Ataxia, Headache, Diplopia, Drowsiness, Nausea, Vomiting, Asthenia

## **Use in Special Populations**

*Pregnancy* : There is definite evidence of risk to the human foetus, but this may be outweighed by the therapeutic benefit for the mother. Pregnant women with epilepsy should be kept under close surveillance. Pregnancy decreased the plasma concentration of Carbamazepine. This is largely the result of an increase in the rate of metabolism. It may therefore be necessary to increase the dose of Carbamazepine during pregnancy in order to maintain a satisfactory clinical response.

*Lactation* : Carbamazepine and its main metabolite, Carbamazepine-10, 11-epoxide, are both present in breast milk of nursing mothers in concentrations of between 30-60% of those in plasma. Breast-feeding is not contraindicated, because the amount of drug ingested by the breastfed infant is too small to cause any adverse pharmacological effects.

## **Commercial Packs**

Epilep<sup>®</sup> Tablet : Each box contains 5 x 10's tablets in blister strips. Each tablet contains Carbamazepine BP 200 mg.

Epilep<sup>®</sup> CR Tablet : Each box contains 5 x 10's tablets in blister strips. Each CR tablet contains Carbamazepine BP 200 mg.