LABTOL®

CARBAMAZEPINE 200mg TABLETS

COMPOSITION:
Each tablet contains: Carbamazepine BP 200mg.

PHARMACOLOGY:
Carbamazepine is a dibenzazepine derivative used as an anticonvulsant and in the treatment of trigeminal neuralgia. It appears to act on seizures reducing polysynaptic responses and blocking the post-tetanic potentiation. The mechanism of action in controlling trigeminal pain of neuralgia is unknown.

PHARMACOKINETICS:
Carbamazepine is slowly and irregularly absorbed from the gastrointestinal tract. It is extensively metabolized in the liver, notably by the cytochrome P 450 isoenzymes CYP3A4 and CYP2C8. One of the primary metabolites, Carbamazepine-10, 11-epoxide is also active. Carbamazepine is excreted in the urine almost entirely in the form of its metabolites, some is also excreted in faeces. Elimination is more rapid in children and accumulation of the active metabolite may often be higher than in adults.Carbamazepine is widely distributed throughout the body and is extensively bound (about 75%) to plasma proteins. It induces its own metabolism so that the plasma half-life may be considerably reduced after repeated administration. The mean plasma half-life of Carbamazepine on repeated administration is about 10-20 hours; its appears to be considerably shorter in children than in adults. It crosses the placental barrier and is distributed into breast milk.

INDICATIONS, DOSAGE AND ADMINISTRATION:
Dosage should be adjusted to the need of the individual patient. A low initial daily dosage with a gradual increase is advised to mimimize side effects. As soon as adequate control is achieved, the dosage may be reduced very gradually to the minimum effective level. Medication should be taken with meals.

EPILEPSY
Adults and Children over 12 years of age:
Initial: 100mg or 200mg once or twice a day. The dosage may be increased up to 2000mg a day at weekly intervals until the best response is obtained.
Maintenance: Adjust dosage to the minimum effective level, usually 800mg - 1200mg a day. (rarely 600mg - 1600mg a day).
Children 6 - 12 Years of age:
Initial: 100mg b.i.d.- increase at weekly intervals by adding to 100mg a day until the optimal response is obtained. Dosage generally should not exceed 100mg daily.
Maintenance: Adjust dosage to the minimum effective level usually 400mg-800mg daily.
Combination Therapy
Carbamazepine may be used alone or with other anticonvulsants. When added to existing anticonvulsants therapy, the drug should be added gradually while the other anticonvulsants are maintaned and gradually decreased except phenytoin, which may have to be increased.

TRIGEMINAL NEURALGIA
Initial: 100mg b.i.d. on the first day, the dosage being increased by up to 200mg a day, using increments of 100mg every 12 hours only as needed until pain is relieved.
Maintenance: 200mg to 1200mg a day (average 400mg-800mg a day) in divided doses.

ADVERSE EFFECTS:
Fairly common side effects of Carbamazepine, particularly in the initial stages of therapy, include: dizziness, drowsiness and ataxia. The effects may be minimized by starting therapy with a low dose.
Gastrointestinal symptoms are less common and include: dry mouth, abdominal pain, nausea and vomiting, anorexia, and diarrhoea or constipation. Generalized erythematous rashes may be severe and may necessitate withdrawal of treatment. Other adverse effects include: photosensitivity reactions, blood disorders, hypersensitivity reactions, hyponatreamia and sometimes oedema.
Overdosage may result in stupor, coma, convulsion, respiratory depression and death.

TREATMENT OF ADVERSE EFFECTS:
In case of overdosage, repeated doses of activated charcoal may be given orally to prevent absorption and also aid elimination. Gastric lavage may be considered if undertaken within 1 hour of ingestion. Supportive and symptomatic therapy may then suffice, with a particular attention to correcting hypoxia and hypotension.

PRECAUTIONS:
Carbamazepine should be avoided in patients with atrioventricular conduction abnormalities and in patients with history of bone marrow depression. It should be given with caution to patients with history of blood disorders or haematological reaction to other drugs or of cardiac, hepatic or renal disease. Caution should be observed in patients with glaucoma or raised intraocular pressure due to its mild antimuscarinic properties. Care is required when withdrawing Carbamazepine. Clinical monitoring is of primary importance throughout treatment. It may produce dizziness and drowsiness, which could impair a patient's ability to drive or operate machinery.

INTERACTIONS:
There are complex interactions between antiepileptics and toxicity may be enhanced without a corresponding increase in antiepileptic activity. Plasma monitoring is often advisable with combination therapy. Carbamazepine is a hepatic enzyme inducer and induces its own metabolism as well as that of a number of other drugs (doxycycline, anticoagulants, oral contraceptives). CYP3A4 inhibitors such as cimetidine and ketoconazole inhibit Carbamazepine metabolism leading to raised plasma concentrations and associated toxicity. Enzyme inducers such as Phenobarbital can enhance the metabolism of Carbamazepine leading to reduced plasma levels.

LEGAL CATEGORY: Prescription only medicines (POM)

THERAPEUTIC CATEGORY: ATC N03-Antipileptics

STORAGE: Store in a dry place below 30ºC. Protect from light. Keep out of reach of children.

SHELF LIFE: As per the product label.

PRESENTATION: Labtol® tablets in packs of 100 and bulk packs of 500 and 1000 tablets.

Date of last review: March 2022

LICENCE HOLDER: LABORATORY & ALLIED LTD.

Manufactured by:
Laboratory & Allied Ltd.
Plot No. 209/10349, Mombasa Road,
P.O. Box 42875, Nairobi, Kenya

LTL010-00