Anleptic®

Carbamazepine BP

COMPOSITION

Anleptic® 200 CR tablet: Each controlled release tablet contains Carbamazepine BP 200 mg.
Anleptic® Suspension: Each 5 ml suspension contains Carbamazepine BP 100 mg.

PHARMACOLOGY
Anleptic® (Carbamazepine) appears to act by reducing polysynaptic responses and blocking the post-tetanic potentiation. It binds with 76% affinity to plasma proteins.

INDICATION
Anleptic® is indicated for-
- partial and secondary
- generalized tonic-clonic seizures
- primary generalized tonic-clonic seizures trigeminal neuralgia
- prophylaxis of bipolar disorder

DOSAGE & ADMINISTRATION
Epilepsy: *Adults and children over 12 years of age - Initial*: Either 200 mg b.i.d. for tablets and XR tablets, or 1 teaspoon q.i.d. for suspension (400 mg/day). Increase at weekly intervals by adding up to 200 mg/day using a b.i.d or a t.i.d. or q.i.d. regimen of the either formulations until the optimal response is obtained. Dosage generally should not exceed 1000 mg daily in children 12-15 years of age, and 1200 mg daily in patients above 15 years of age. Doses up to 1600 mg daily have been used in adults in rare instances. Maintenance: usually 800-1200 mg daily. *Children 6-12 years of age - Initial*: Either 100 mg b.i.d. for tablets or XR tablets, or 1/2 teaspoon q.i.d. for suspension (200 mg/day). Increase at weekly intervals by adding up to 100 mg/day using a b.i.d. or a t.i.d. or q.i.d. regimen of the either formulations until the optimal response is obtained. Dosage generally should not exceed 1000 mg daily. Maintenance: usually 400-800 mg daily. *Children under 6 years of age - Initial:* 10-20 mg/kg/day b.i.d. or t.i.d. as tablets, or q.i.d. as suspension. Increase weekly to achieve optimal clinical response administered t.i.d. or q.i.d. Maintenance: Ordinarily, optimal clinical response is achieved at daily doses below 35 mg/kg. If satisfactory clinical response has not been achieved, plasma levels should be measured to determine whether or not they are in the therapeutic range. No recommendation regarding the safety of Carbamazepine for use at doses above 35 mg/kg/24 hours can be made.
Combination therapy: Carbamazepine may be used alone or with other anticonvulsants. When added to existing anticonvulsant therapy, the drug should be added gradually while the other anticonvulsants are maintained or gradually decreased, except phenytoin, which may have to be increased.
Trigeminal Neuralgia: *Initial*: On the first day, either 100 mg b.i.d. for tablets or XR tablets, or 1/2 teaspoon q.i.d. for suspension, for a total daily dose of 200 mg. This daily dose may be increased by up to 200 mg/day using increments of 100 mg every 12 hours for tablets or XR tablets, or 50 mg (1/2 teaspoon) q.i.d. for suspension, only as needed to achieve freedom from pain. A total dose of 1200 mg daily shouldn't be exceeded. *Maintenance*: Control of pain can be maintained in most patients with 400-800 mg daily. However, some patients may be maintained on as little as 200 mg daily, while others may require as much as 1200 mg daily. At least once every 3 months throughout the treatment period, attempts should be made to reduce the dose to the minimum effective level or even to discontinue the drug.
The tablets or syrup can be taken without regards to meal.

CONTRAINDICATION
This medicine should not be used if anybody is allergic to one or any of its ingredients. It can not be used also in the following conditions:
- Problems with the electrical message pathways in the heart (atrioventricular block)
- History of decreased blood cell production by the bone marrow (bone marrow depression)
- Hereditary blood disorders called porphyrias
- Allergy to tricyclic antidepressants
- People who have taken a monoamine-oxidase inhibitor antidepressant (MAOI) in the last 14 days

WARNINGS & PRECAUTION
Warning:
This medicine may cause dizziness and drowsiness. Special care should be taken while performing potentially hazardous activities, such as driving or operating machinery.
This medicine may cause skin reactions. If any rash, skin peeling, itching, or other unexplained skin reaction is seen while taking this medicine the concerned doctor should be informed immediately. This medicine may rarely cause liver problems. For this reason, consultation with doctor is needed if unexplained itching, yellowing of the skin or eyes, unusually dark urine, nausea and vomiting, abdominal pains, and loss of appetite or flu-like symptoms.Carbamazepine decreases the blood levels of hormonal contraceptives containing estrogen and/or progesterone, which may make the contraceptive ineffective or result in breakthrough bleeding. Women taking this medicine who require contraception should be prescribed a contraceptive containing at least 50 micrograms of oestrogen, or use non-hormonal methods of contraception, such as condoms.Taking this medicine should not be stopped suddenly unless the doctor tells. Otherwise, as suddenly stopping treatment is likely to make the symptoms return. If this medicine is stopped, it should normally be done gradually, under the supervision of a specialist.

Caution:
Mixed seizures including absence seizures-
Elderly people
- History of heart disease
- History of kidney disease
- History of liver disease
- History of psychotic illness
- Raised pressure in the eye (intraocular pressure), eg. glaucoma
- History of blood disorders that were caused by any other medication
- History of previous Carbamazepine therapy that was interrupted due to side effects or allergy.

SIDE EFFECT
Dizziness, drowsiness, ataxia, dry mouth, abdominal pain, nausea, vomiting, anorexia, leucopenia, proteinuria, bradycardia, heart failure and hypotension. Erythematous skin rash, aplastic anemia may also be observed.

ADVERSE EFFECT
The most severe adverse reactions have been observed in the hemopoietic system, the skin and the cardiovascular system. The most frequently observed adverse reactions, particularly during the initial phases of therapy, are dizziness, drowsiness, unsteadiness, nausea, and vomiting. This medicine may cause increased sensitivity to the sun. Exposure to the sun, sunlamps, or tanning booths should be avoided if the increased sensitivity is seen. A sunscreen or protective clothing may be helpful at outside for a prolonged period.

DRUG INTERACTION
Galactorrhoea has been reported in few women on oral contraceptives within the first two months of Carbamazepine treatment. Hepatic enzyme inducers such as Carbamazepine and Phenytoin may interact with Carbamazepine by increasing its metabolism. So an increase in dosage of Carbamazepine may be required.

USE IN PREGNANCY AND LACTATION
Pregnancy category D. Carbamazepine and its epoxide metabolite are transferred to breast milk. Because of the potential serious side effects, decision should me made whether to discontinue nursing or discontinue the drug.

STORAGE
Store at a cool & dry place, protected from light. Keep all medicines out of the reach of the children.

HOW SUPPLIED
Anleptic® 200 CR tablet: Each box contains 50 tablets in blister packs.
Anleptic® suspension: Each bottle contains 100 ml suspension in PET bottle.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Kaliakoir, Gazipur, Bangladesh