PACKAGE INSERT

SCHEDULING STATUS:

S3

Zecarb 200 Tablets

COMPOSITION

Each tablet contains 200 mg carbamazepine

PHARMACOLOGICAL CLASSIFICATION

A 2.5 Anticonvulsants, including anti-epileptics.

PHARMACOLOGICAL ACTION

Carbamazepine is a derivative of iminostilbene with a carbamyl group at the 5-position; this moiety is responsible for the anti-epileptic activity of carbamazepine.

Carbamazepine is absorbed slowly and erratically after oral ingestion. Peak concentrations in plasma are observed 4 to 8 hours after oral ingestion, but may be delayed as much as 24 hours especially following the administration of a large dose. Carbamazepine distributes rapidly into all tissues.

Binding to plasma proteins occurs to the extent of about 75 %. Concentration in the cerebrospinal fluid appears to correspond to the concentration of the free carbamazepine in plasma. The predominant pathway of metabolism involves conversion to the 10, 11-epoxide active metabolite. The 10, 11- epoxide is metabolised further to inactive compounds, which are excreted in the urine principally as glucoronides. The half-life of the parent compound in plasma during long-term therapy averages between 10 and 20 hours. Because of drug-metabolising enzymes, the half-life is much longer in individuals who have received only a single dose. The half- life of the 10, 11 -epoxide is somewhat shorter than that of the parent compound. Less than 3 % of carbamazepine is recovered in the urine as the parent compound or the epoxide.

INDICATIONS

Zecarb 200 is indicated for use in patients with generalised tonic-clonic and both simple and complex partial seizures.

Zecarb 200 is also used in the treatment of trigeminal neuralglia.

CONTRA-INDICATIONS

Hypersensitivity to carbamazepine.

Patients with atrioventricular conduction abnormalities unless paced.

Should not be given to patients with liver damage.

Pregnancy and lactation: In woman of childbearing age, anticonvulsant therapy should wherever possible prescribed as monotherapy. If pregnancy occurs in a woman receiving carbamazepine, the potential benefits if therapy must be carefully weighed against its possible hazards, particularly in the first three months of pregnancy.

The safety of carbamazepine in pregnancy has not been demonstrated. Safety in lactation has not been established. Carbamazepine passes into breast milk.

Carbamazepine should not be given to patients taking a monoamine oxidase inhibitor or within 14 days of stopping such treatment.

WARNINGS

Drowsiness and dizziness may occur especially at initiation of therapy. Patients must be warned against driving or performing tasks where loss of concentration may lead to accidents.

Carbamazepine should not be given to patients taking a monoamine oxidase inhibitor or within 14 days of stopping such treatment.

DOSAGE AND DIRECTIONS FOR USE

The dosage of ZECARB 200 should be adjusted to the needs of the individual patient to achieve adequate control of seizures.

Withdrawal of carbamazepine or transition to or from another type of anti-epileptic should be

made gradually to avoid precipitating an increase in the frequency of seizures.

The time and manner of taking carbamazepine should be standardised for the patient since variations might affect absorption with consequent fluctuations in the plasma concentrations.

The suggested initial oral dose is 100 to 200 mg once or twice daily gradually increased to a usual maintenance dose of 0.8 to 1.2 g daily in divided doses; 2-4 times daily up to 1.6 g may occasionally be necessary. Weekly increments of 200 mg per day is recommended.

Suggested daily doses for children:
Up to 1 year of age: 100 to 200 mg
1 to 5 years: 200 to 400 mg
5 to 10 years: 400 to 600 mg
10 to 15 years: 600 mg to 1 g
Since carbamazepine has no long plasma half-life, a twice daily dosage regimen is usually adequate to maintain an effective plasma concentration.

A low initial dose is recommended to minimize side-effects.
Trigeminal neuralgia:
Suggested initial dose:
100 mg twice daily increased gradually to a maximum of 1.6 g daily.

SIDE EFFECTS AND SPECIAL PRECAUTIONS

Fairly common side effects of carbamazepine, particularly in the initial stages of therapy, include dizziness, drowsiness and ataxia. these effects may be minimized by starting therapy with a low dose.
Drowsiness and disturbances of cerebellar and oculo-motor function (with ataxia, nystagmus and diplopia) are also symptoms of excessive plasma concentrations of carbamazepine and

may disappear with continued treatment at reduced dosage.

Gastro-intestinal symptoms include dry mouth, gastric distress and abdominal pain, nausea and vomiting, anorexia, and diarrhoea or constipation.

Generalised erythematous rashes, which may be severe may occur and may necessitate withdrawal of treatment. Photosensitivity reactions, urticaria, exfoliative dermatitis, erythema multiform, and the Stevens-Johnson syndrome, and lupus erythematosus have also been reported.

Blood disorders reported include agranulocytosis, aplastic anaemia, eosinophilia, leucopenia, leucocytosis, thrombocytopenia, and purpura. Lymphadenopathy, splenomegaly, pneumonitus, abnonmalities of liver and kidney function, and jaundice have occurred.

Other side effects reported include paraesthesia, headache, arrythmias, heart block, congestive heart failure, water intoxication and dystonias and dyskinesias with asterixis. Carbamazepine should be given with caution to patients with a history of blood disorders or of cardiac, hepatic or renal disease.

Precautions:

Since carbamazepine has mild anticholinergic properties, caution should be observed in patients with raised intra-ocular pressure. Patients should be examined periodically for eye changes.

Carbamazepine is extensively bound to plasma proteins and is therefore susceptible to interactions with medicines liable to compete for similar binding sites.

Carbamazepine is an enzyme inducer and induces its own metabolism as well as that of a

number of other medicines, including some antibiotics, anticoagulants, and sex hormones (notably, oral contraceptives).

Carbamazepine and phenytoin may also mutually enhance one another's metabolism. The metabolism of Carbamazepine is similarly enhanced by enzyme inducers such as phenobarbitone.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See side effects listed. Treatment of over dosage is symptomatic and supportive.

IDENTIFICATION

White to off-white, round, biconvex, uncoated tablets plain on both the sides.

PRESENTATION

Zecarb 200 Tablets are available in unit cartons containing 9 x 10 (90's), 6 x 14 (84's), 4 x 14 (56's) or 2 x 14 (28's) aluminium foil strip packs.

STORAGE INSTRUCTIONS

Store at or below 25 °C in a dry place.

Keep out of reach of children.

REGISTRATION NUMBER

29/2.5/0195

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