Only for the use of Medical Professionals

Serontin®

Ethosuximide

Description

Serontin® is a preparation of Ethosuximide which is an anticonvulsant. It suppresses the paroxysmal spike and wave pattern common to absence seizures. The frequency of epileptiform attacks is reduced apparently by depression of the motor cortex and elevation of the threshold of the central nervous system to convulsive stimuli. Compared with other succinimide anticonvulsants, Serontin® is more specific for pure absence seizures.

Indication and usage

Serontin® is indicated for the control of absence seizures

Dosage and administration

Pediatric Patients

Children 3 to 6 years of age: Initially 5 ml (250 mg) daily in a single dose
Children ≥6 years of age: Initially 10 ml (500 mg) daily in a single dose or divided doses

Dosage should be increased by small increments, by 5 ml (250 mg) every 4–7 days until seizure control is achieved with minimal adverse effects. Dosage usually should not be >30 ml (1.5 g) daily, given in divided doses. If dosage is >1.5 g daily, clinician must closely supervise patient.

Usual maintenance dosage: 20 mg/kg or 1.2 g/m^2 daily

Adults

Initially 10 ml (500 mg) daily in a single dose or divided doses

Dosage should be increased by small increments, by 5 ml (250 mg) every 4–7 days until seizure control is achieved with minimal adverse effects. Dosage usually should not be >30 ml (1.5 g), given in divided doses.

Usual maintenance dosage: 20 mg/kg or 1.2 g/m^2 daily

Use in pregnancy and lactation

Ethosuximide crosses the placenta. Risk-benefit ratio should be weighed in treating or counseling epileptic women of childbearing potential.
Ethosuximide is excreted in breast milk. It should be used in nursing mothers only if the benefits clearly outweigh the risks. Breast feeding is best avoided.

Side effects

The common side effects of ethosuximide are gastro-intestinal disturbances including nausea, vomiting, diarrhoea, abdominal pain, anorexia, weight loss. The less frequent side effects are headache, fatigue, drowsiness, dizziness, hiccup, ataxia, mild euphoria, irritability, aggression, impaired concentration; rarely tongue swelling, sleep disturbances, night terrors, depression, psychosis, photophobia, dyskinesia, increased libido, vaginal bleeding, myopia, gingival hypertrophy, and rash; hyperactivity, increase in seizure frequency, blood disorders such as leucopenia, agranulocytosis, pancytopenia, and aplastic anaemia, systemic lupus erythematosus, and Stevens-Johnson syndrome.

Precautions
Ethosuximide should be used with caution in hepatic or renal impairment. Ethosuximide may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving or other such activities requiring alertness. Therefore, the patient should be cautioned accordingly. Abrupt withdrawal should be avoided. Patients should be monitored for signs of suicidal ideation & behaviors and appropriate treatment should be considered.

Drug interactions
The plasma concentrations of ethosuximide may be reduced by carbamazepine, primidone, phenobarbitone and lamotrigine and increased by isoniazid. No consistent changes in levels of ethosuximide occur when used in combination with phenytoin or sodium valproate. Phenytoin levels however are increased by concomitant ethosuximide.

Contraindications
Ethosuximide should not be used in patients with hypersensitivity to succinimides (e.g. methosuximide, phenosuximide) & known hypersensitivity to the active substance or to any of the excipients.

Overdose
Acute overdoses may produce nausea, vomiting and CNS depression including coma with respiratory depression. Relationship between ethosuximide toxicity and its plasma levels has not been established.

Pharmaceutical precautions
Keep away from the reach of children. Store in a cool and dry place protected from light.

Presentation
Serontin® Syrup: Each 5 ml contains Ethosuximide USP 250 mg

Packaging
Serontin® Syrup: Bottle of 70 ml

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