

Composition

PeranelTM 2 tablet: Each film coated tablet contains Perampanel INN 2 mg.

PeranelTM 4 tablet: Each film coated tablet contains Perampanel INN 4 mg.

Pharmacology

Perampanel is a non-competitive antagonist of the ionotropic α -amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid (AMPA) glutamate receptor on post-synaptic neurons. Glutamate is the primary excitatory neurotransmitter in the central nervous system and is implicated in a number of neurological disorders caused by neuronal over excitation.

The precise mechanism by which Perampanel exerts its antiepileptic effects in humans is unknown.

Indication: Perampanel an anti-epileptic drug is indicated for:

- Treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy from 4 years of age and older.
- Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in patients with epilepsy from 12 years of age and older.

Dosage & Administration

Perampanel can be taken without regards to food. Dosage of Perampanel is as follows-

- Starting dose: 2 mg once daily at bedtime. May increase dose based on clinical response and tolerability by increments of 2 mg once daily no more frequently than at weekly intervals.
- Recommended maintenance dose in monotherapy or adjunctive therapy for partial-onset seizures: 8 mg to 12 mg once daily at bedtime.
- Recommended maintenance dose in adjunctive therapy for primary generalized tonic-clonic seizures: 8 mg once daily at bedtime.

Mild and Moderate Hepatic Impairment: Maximum recommended daily dose is 6 mg (mild) and 4 mg (moderate) once daily at bedtime.

Severe Hepatic Impairment: Not recommended.

Severe Renal Impairment: Not recommended

Elderly: Increase dose no more frequently than every 2 weeks.

Adverse Effects

Perampanel may cause Serious Psychiatric and Behavioral Reactions, Suicidal Behavior and Ideation, Dizziness, Somnolence, Fatigue, Irritability, Falls, Nausea, Ataxia, Balance Disorder etc.

Special warnings and precautions for use

- Suicidal Behavior and Ideation: Monitor for suicidal thoughts or Behaviour.
- Neurologic Effects: Monitor for dizziness, gait disturbance, somnolence and fatigue.
- Falls: Monitor for falls and injuries.
- Drug Reaction with Eosinophilia and Systemic Symptoms / Multi-Organ Hypersensitivity: Discontinue if no alternate etiology.
- Withdrawal of Antiepileptic Drugs: In patients with epilepsy, there may be an increase in seizure frequency.

Contraindication

None.

Drug interaction

- Contraceptives: 12 mg once daily may decrease the effectiveness of hormonal contraceptives containing levonorgestrel.
- Moderate and Strong CYP3A4 Inducers (including carbamazepine, oxcarbazepine, and phenytoin): increase clearance of Perampanel and decrease Perampanel plasma concentrations.

Use in pregnancy and lactation

Pregnancy: Based on animal data, may cause fetal harm.

Lactation: There are no data on the presence of perampanel in human milk, the effects on the breastfed child, or the effects of the drug on milk production.

Storage

Protect from light and moisture, store below 30° C. Keep out of the reach of children.

How Supplied

PeranelTM 2 tablet: Each Box contains 20 tablets in blister pack

PeranelTM 4 tablet: Each Box contains 20 tablets in blister pack

Manufactured by:

