

Brivaracetam INN

Composition

Briva 25 Tablet: Each film-coated tablet contains Brivaracetam INN 25 mg.

Briva 50 Tablet: Each film-coated tablet contains Brivaracetam INN 50 mg.

Briva Oral Solution: Each ml contains Brivaracetam INN 10 mg.

Pharmacology

The precise mechanism by which Brivaracetam exerts its anticonvulsant activity is not known. Brivaracetam displays a high and selective affinity for synaptic vesicle protein 2A (SV2A) in the brain, which may contribute to the anticonvulsant effect. Brivaracetam exhibits linear and time-independent pharmacokinetics at the approved doses. Brivaracetam is highly permeable and is rapidly and almost completely absorbed after oral administration. Brivaracetam is rapidly and evenly distributed in most tissues. More than 95% of the dose, including metabolites, is excreted in the urine.

Indications

- ✓ Epilepsy
- ✓ Partial-Onset of Seizure including
 - Focal Impaired Awareness or Complex Partial Seizures
 - Focal Aware or Simple Partial Seizure
- ✓ Secondarily Generalized Seizures or Bilateral Tonic Clonic Seizure

Dosage and Administration:

Route of Administration: Orally

Monotherapy or Adjunctive Therapy

The recommended dosage for adults and pediatric patients 4 years of age and older is included in below table. In pediatric patients (> 4 years to < 16 years of age), the recommended dosing regimen is dependent upon body weight. When initiating treatment, gradual dose escalation is not required. Dosage should be adjusted based on clinical response and tolerability.

Recommended Dosage for Adults and Pediatric Patients 4 Years and Older

Age and Body Weight	Initial Dosage	Minimum and Maximum Maintenance Dosage
Adults (16 years and older)	50 mg twice daily (100 mg per day)	25 mg to 100 mg twice daily (50 to 200 mg per day)
Pediatric patients weighing 50 kg or more	25 mg to 50 mg twice daily (50 mg to 100 mg per day)	25 mg to 100 mg twice daily (50 to 200 mg per day)
Pediatric patients weighing 20 kg to less than 50 kg	0.5 mg/kg to 1 mg/kg twice daily (1 mg/kg to 2 mg/kg per day)	0.5 mg/kg to 2 mg/kg twice daily (1 mg/kg to 4 mg/kg per day)
Pediatric patients weighing 11 kg to less than 20 kg	0.5 mg/kg to 1.25 mg/kg twice daily (1 mg/kg to 2.5 mg/kg per day)	0.5 mg/kg to 2.5 mg/kg twice daily (1 mg/kg to 5 mg/kg per day)

Geriatric Use

Dose selection for an elderly patient should be judicious, usually starting at the low end of the dosing range.

Renal Impairment

Dose adjustment of Brivaracetam is not required for patients with impaired renal function. Use of Brivaracetam is not recommended in patients with end-stage renal disease undergoing dialysis.

Hepatic Impairment

For all stages of hepatic impairment, the recommended starting dosage of Brivaracetam is 25 mg twice daily (50 mg per day) and the recommended maximum dosage is 75 mg twice daily (150 mg per day).

OR AS DIRECTED BY THE PHYSICIAN

Contraindications

Contraindicated in patient with hypersensitivity to Brivaracetam or any of the inactive ingredients in Brivaracetam.

Warnings and Precautions

Like other antiepileptic drugs, Brivaracetam may cause suicidal thoughts or actions in a very small number of people. Patients should be restricted from driving or operating machinery until they have gained sufficient experience on Brivaracetam. Brivaracetam should be gradually withdrawn. If Bronchospasm and Angioedema develops, should seek immediate medical care.

Side Effects

Adults:

Common Side Effects: Sedation, Dizziness, Drowsiness, Fatigue and Nausea or Vomiting etc.

Rare Side Effects: Cerebellar coordination and balance disturbances, Mood swings, Anxiety, Hallucination, Delusion, Irritability, Constipation, Bronchospasm, Decreased Neutrophils, Decreased White Blood Cells, Giant Hives etc.

Pediatric Patients: Most common adverse reactions are similar to those seen in adult patients.

Pregnancy and Lactation

Pregnancy: Pregnancy Category of Brivaracetam is C. There is no adequate and well-controlled studies in pregnant women. Brivaracetam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation: No data are available regarding the presence of Brivaracetam in human milk, the effects on the breastfed infant or the effects of the drug on milk production.

Use in Children and Adolescent

Safety and effectiveness in pediatric patients below the age of 4 years have not been established.

Drug Interactions

With Medicine:

Rifampin: Because of decreased concentrations, increasing Brivaracetam dosage in patients on concomitant Rifampin is recommended.

Carbamazepine: Consider reducing Carbamazepine dosage in patients on concomitant Brivaracetam.

Phenytoin: Phenytoin levels should be monitored in patients on concomitant Brivaracetam.

With Food and Others: Food does not affect the extent of Brivaracetam absorption. Brivaracetam can be taken with or without food. Use of alcohol during Brivaracetam therapy is not recommended.

Overdose

There is limited clinical experience with Brivaracetam overdose in humans. Vertigo, balance disorder, fatigue, nausea, diplopia, anxiety, and bradycardia were reported as adverse reaction of Brivaracetam overdose.

Storage

Store below 30° C temperature and in a dry place, protected from light.

Keep all medicines out of reach of children.

Do not freeze the oral solution.

Packing

Briva 25 Tablet: Each Box contains 1X10 Tablets in Alu-Alu blister.

Briva 50 Tablet: Each Box contains 1X10 Tablets in Alu-Alu blister.

Briva Oral Solution: Each box contains a bottle containing 50 ml oral solution and a measuring cup.

* Further information is available on request.

07 1424/01



Manufactured by:
The ACME Laboratories Ltd.
Dhulwila, Dhamrai, Dhaka, Bangladesh
For Health, Vigour and Happiness