

EpicureTM

Brivaracetam Tablet, Oral Solution & Injection

Presentation

EpicureTM 25 Tablet: Each tablet contains Brivaracetam INN 25 mg.
EpicureTM 50 Tablet: Each tablet contains Brivaracetam INN 50 mg.
EpicureTM Oral Solution: Each 5 ml solution contains Brivaracetam INN 50 mg.
EpicureTM 50 Injection: Each 5 ml injectable solution contains Brivaracetam INN 50 mg.

Description

The precise mechanism by which Brivaracetam exerts its anti-convulsant 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 anti-convulsant effect.

Indications and usage

Brivaracetam is indicated for the treatment of partial onset seizures in patients 1 month of age and older.

Dosage and administration

Recommended Dosage for Patients 1 Month of Age 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)	
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)
Pediatric patients weighing less than 11 kg	0.75 mg/kg to 1.5 mg/kg twice daily (1.5 mg/kg to 3 mg/kg per day)	0.75 mg/kg to 3 mg/kg twice daily (1.5 mg/kg to 6 mg/kg per day)

Administration instruction of Brivaracetam injection: Brivaracetam injection may be used for adult patients when oral administration is temporarily not feasible. It can be administered intravenously without further dilution or may be mixed with diluents e.g. 0.9% Sodium Chloride injection/Lactated Ringer's injection/5% Dextrose injection. It should be administered intravenously over 2 to 15 minutes.

Side-effects

The most common side-effects of Brivaracetam are nausea, vomiting, constipation, somnolence, sedation, dizziness, fatigue, irritability etc.

Contraindications

Brivaracetam is contraindicated in patients with a known hypersensitivity to either Brivaracetam or to any excipients in Brivaracetam.

Precautions

Monitor patients for suicidal behavior and ideation, neurologic adverse reactions (somnolence & fatigue), psychiatric adverse reactions (irritability, depression, aggressive behavior, anxiety), hypersensitivity (bronchospasm & angioedema) when Brivaracetam is prescribed.

Drug interactions

Brivaracetam should be used with caution in combination with Rifampin, Carbamazepine, Phenytoin etc.

Use in pregnancy and lactation

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

Lactation: Brivaracetam is excreted in human breast milk. The known benefits of breastfeeding should be weighed against the unknown risks of infant exposure to Brivaracetam.

Use in special population

Pediatric use: Safety and effectiveness of Brivaracetam has not established in pediatric patients below the age of 1 month.

Geriatric use: Start at the low end of the dosing range.

Renal impairment: No dose adjustment is necessary for patients with impaired renal function.

Hepatic impairment: Because of increases in Brivaracetam exposure, dosage adjustment is recommended for all stages of hepatic impairment.

Overdose

Overdose of Brivaracetam is limited and there is no specific antidote to Brivaracetam. If overdose occurs, standard medical practice for the management of overdose should be used.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack

EpicureTM 25 Tablet: Each box contains 1 blister strip of 10 tablets.

EpicureTM 50 Tablet: Each box contains 1 blister strip of 10 tablets.

EpicureTM Oral Solution: Each bottle contains 50 ml of Brivaracetam Oral Solution.

EpicureTM 50 Injection: Each box contains 1 vial of 5 ml injection.