BRITZILAM

Abbreviated Prescribing information for Brivaracetam Injection 10mg/ml [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Brivaracetam displays a high and selective affinity for synaptic vesicle protein 2A (SV2A), a transmembrane glycoprotein found at presynaptic level in neurons and in endocrine cells. Although the exact role of this protein remains to be elucidated it has been shown to modulate exocytosis of neurotransmitters. Binding to SV2A is believed to be the primary mechanism for brivaracetam anticonvulsant activity.

INDICATIONS: As adjunctive therapy in the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.

DOSAGE AND ADMINISTRATION: Brivaracetam may be initiated with either intravenous or oral administration. When converting from oral to intravenous administration or vice versa, the total daily dose and frequency of administration should be maintained. Brivaracetam solution for injection/infusion is an alternative for patients when oral administration is temporarily not feasible.

The recommended starting dose is either 50 mg/day or 100 mg/day based on physician assessment of required seizure reduction versus potential side effects. The dose should be administered in two equally divided doses, once in the morning and once in the evening. Based on individual patient response and tolerability, the dose may be adjusted in the dose range of 50 mg/day to 200 mg/day.

There is no experience with twice daily intravenous administration of brivaracetam for a period longer than 4 days.

WARNINGS & PRECAUTIONS: Suicidal ideation and behavior, hepatic impairment, contains lactose, contains sodium.

ADVERSE REACTIONS: influenza, neutropenia, decreased appetite, type I hypersensitivity, depression, anxiety, insomnia, irritability, suicidal ideation, psychotic disorder, aggression, agitation, dizziness, somnolence, convulsion, vertigo, upper respiratory tract infections, cough, nausea, vomiting, constipation, fatigue.

MARKETED BY:



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IN/BRITZILAM 10mg/ml/MAR-21/01/ABPI

(Additional information is available on request)