BRITZILAM

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for BRITZILAM [Brivaracetam Oral Solution I.P. 10 mg/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: It is indicated as adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy.

DOSAGE AND ADMINISTRATION: The recommended starting dose is either 50 mg/day or 100 mg/day based on physician's assessment of required seizure reduction versus potential side effects. Based on individual patient response and tolerability, the dose may be adjusted in the effective dose range of 50 mg/day to 200 mg/day.

Brivaracetam oral solution can be diluted in water or juice shortly before swallowing and may be taken with or without food. A nasogastric tube or a gastrostomy tube may be used when administering brivaracetam oral solution.

CONTRAINDICATION: Hypersensitivity to the active substance or other pyrrolidone derivatives or to any of the excipients**.**

WARNINGS & PRECAUTIONS: Suicidal ideation and behaviour have been reported in patients treated with antiepileptic drugs (AEDs), including brivaracetam, in several indications. Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered.

Dose adjustments are recommended for patients with hepatic impairment. Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS), which can be life-threatening or fatal, have been reported in association with brivaracetam treatment. At the time of the prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, brivaracetam should be withdrawn immediately and an alternative treatment should be considered.

DRUG INTERACTIONS: Brivaracetam approximately doubled the effect of alcohol on psychomotor function, attention and memory. Intake of brivaracetam with alcohol is not recommended. Brivaracetam plasma concentrations are decreased when co-administered with strong enzyme inducing AEDs (carbamazepine, phenobarbital, phenytoin) but no dose adjustment is required. Other strong enzyme inducers (such as St John´s wort (Hypericum perforatum)) may also decrease the systemic exposure of brivaracetam. Therefore, starting or ending treatment with St John's wort should be done with caution. Brivaracetam is a moderate reversible inhibitor of epoxide hydrolase resulting in an increased concentration of carbamazepine epoxide, an active metabolite of carbamazepine.

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

vomiting, constipation**,** stevens-johnson syndrome, and fatigue.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/BRITZILAM 10mg/mL/APR 2026/02/PI

(Additional information is available on request)