BRITZILAM SR

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory
abbreviated prescribing information for BRITZILAM SR (Brivaracetam Sustained Release Tablets 200 mg)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: 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.

INDICATION: 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: Brivaracetam Sustained Release 200 mg Tablets is recommended once daily or as directed by physician.

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

WARNINGS & PRECAUTIONS: ***Suicidal ideation and behavior:*** Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic drugs (AEDs), including brivaracetam, in several indications. A meta-analysis of randomized placebo-controlled trials of AEDs has also shown a small increased risk of suicidal ideation and behaviour. ***Hepatic impairment*:** There are limited clinical data on the use of brivaracetam in patients with pre-existing hepatic impairment. Dose adjustments are recommended for patients with hepatic impairment. ***Excipients: Lactose intolerance:*** Brivaracetam film-coated tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

DRUG INTERACTIONS: ***Rifampin*** Co-administration with rifampin decreases BRIVARACETAM plasma concentrations likely because of CYP2C19 induction. ***Carbamazepine:*** Co-administration with carbamazepine may increase exposure to carbamazepine-epoxide, the active metabolite of carbamazepine. ***Phenytoin:*** Because BRIVARACETAM can increase plasma concentrations of phenytoin. ***Levetiracetam:*** BRIVARACETAM provided no added therapeutic benefit to levetiracetam when the two drugs were co-administered.

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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TORRENT PHARMACEUTICALS LTD.
IN/ BRITZILAM SR 200mg/FEB-23/01/ABPI
(Additional information is available on request)