

## **BRITZILAM**

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.**

Abbreviated Prescribing information for BRITZILAM (Brivaracetam Oral Solution  
10mg/mL)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### **PHARMACOLOGICAL PROPERTIES:**

**Mechanism of action:** The precise mechanism by which Brivaracetam exerts its anticonvulsant activity is not known. Brivaracetam displays a high and selective affinity for synaptic vesicle protein2A (SV2A) in the brain, which may contribute to the anticonvulsant effect.

**DOSAGE AND ADMINISTRATION:** The recommended dosage for adults and patients 16 years of age and older is 50 mg twice daily (100 mg per day) initially and Minimum and Maximum Maintenance Dosage are 25 mg to 100 mg twice daily (50 to 200 mg per day). As directed by physician.

**CONTRAINDICATION:** Hypersensitivity to brivaracetam or any of the inactive ingredients in BRITZILAM (bronchospasm and angioedema have occurred).

**WARNINGS & PRECAUTIONS: Suicidal Behavior and Ideation:** Antiepileptic drugs (AEDs), including Brivaracetam, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. **Neurological Adverse Reactions:** Somnolence and Fatigue, Dizziness and Disturbance in Gait and Coordination. **Psychiatric Adverse Reactions, Hypersensitivity: Bronchospasm and Angioedema, Withdrawal of Antiepileptic Drugs.**

**DRUG INTERACTION: Rifampin:** Co-administration with rifampin decreases Brivaracetam plasma concentrations likely because of CYP2C19 induction, **Carbamazepin:** Co-administration with carbamazepine may increase exposure to carbamazepine-epoxide, the active metabolite of carbamazepine. **Phenytoin:** Because Brivaracetam can increase plasma concentrations of phenytoin, phenytoin levels should be monitored in patients when concomitant Brivaracetam is added to or discontinued from ongoing phenytoin therapy. **Levetiracetam:** Brivaracetam provided no added therapeutic benefit to levetiracetam when the two drugs were co-administered.

**ADVERSE REACTIONS: Gastrointestinal disorders:** Nausea/vomiting symptoms, Constipation, **Nervous system disorders:** Somnolence and sedation, Dizziness, Fatigue, Cerebellar coordination and balance disturbances, **Psychiatric disorders:** Irritability.

### **Manufactured by:**

Hetero Labs Limited  
At plot no. 47B/2, Phase-1, IDA,  
Cherlapally, Medchal  
Malkajgiri – 500051.

**IN/ BRITZILAM 10mg/mL /APR-21/01/ABPI**

(Additional information is available on request)