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

BRITZILAM

1. Generic Name

BRIVARACETAM Oral Solution 10mg/mL

2. Qualitative and quantitative composition

Each ml contains:
Brivaracetam…….10mg
Preservative:
Methyl Paraben I.P. ……1mg/mL

The excipients used are Sucralose, Sorbitol, Glycerin, Propylene glycol, Peppermint supreme & Raspberry Classic.

3. Dosage form and strength

Dosage Form: Oral Solution

Strength: 10mg/mL

4. Clinical particulars

4.1 Therapeutic indication

BRITZILAM is indicated as adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy.

4.2 Posology and method of administration

Monotherapy or Adjunctive Therapy: The recommended dosage for adults and patients 16 years of age and older is included. When initiating treatment, gradual dose escalation is not required. Dosage should be adjusted based on clinical response and tolerability.

Recommended Dosage for Adults and Patients 16 Years 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)

BRITZILAM oral solution may be taken with or without food.
BRITZILAM Oral Solution:
A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device. When using BRITZILAM oral solution, no dilution is necessary. BRITZILAM oral solution may also be administered using a nasogastric tube or gastrostomy tube. Discard any unused BRITZILAM oral solution remaining after 5 months of first opening the bottle.

4.3 Contraindications

Hypersensitivity to BRIVARACETAM or any of the inactive ingredients in BRITZILAM (bronchospasm and angioedema have occurred).

4.4 Special warnings and precautions for use

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. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior.

Pooled analyses of 199 placebo-controlled clinical trials (mono-and adjunctive therapy) of 11 different AEDs showed that patients randomized to one of the AEDs had approximately twice the risk (adjusted Relative Risk 1.8, 95% CI:1.2, 2.7) of suicidal thinking or behavior compared to patients randomized to placebo. In these trials, which had a median treatment duration of 12 weeks, the estimated incidence rate of suicidal behavior or ideation among 27,863 AED-treated patients was 0.43%, compared to 0.24% among 16,029 placebo-treated patients, representing an increase of approximately one case of suicidal thinking or behavior for every 530 patients treated. There were four suicides in drug-treated patients in the trials and none in placebo-treated patients, but the number is too small to allow any conclusion about drug effect on suicide.

The increased risk of suicidal thoughts or behavior with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment assessed. Because most trials included in the analysis did not extend beyond 24 weeks, the risk of suicidal thoughts or behavior beyond 24 weeks could not be assessed.

The risk of suicidal thoughts or behavior was generally consistent among drugs in the data analyzed. The finding of increased risk with AEDs of varying mechanisms of action and across a range of indications suggests that the risk applies to all AEDs used for any indication. The risk did not vary substantially by age (5-100 years) in the clinical trials analyzed. Table 2 shows absolute and relative risk by indication for all evaluated AEDs.

Risk of Suicidal Thoughts or Behaviors by Indication for Antiepileptic Drugs in the Pooled Analysis

Indication	Placebo Patients with Events Per 1000 Patients	Drug Patients with Events Per 1000 Patients	Relative Risk: Incidence of Events in Drug Patients/Incidence in Placebo Patients	Risk Difference: Additional Drug Patients with Events Per 1000 Patients
Epilepsy	1.0	3.4	3.5	2.4
Psychiatric	5.7	8.5	1.5	2.9
Other	1.0	1.8	1.9	0.9
Total	2.4	4.3	1.8	1.9

The relative risk for suicidal thoughts or behavior was higher in clinical trials in patients with epilepsy than in clinical trials in patients with psychiatric or other conditions, but the absolute risk differences were similar for the epilepsy and psychiatric indications.
Anyone considering prescribing BRIVARACETAM or any other AED must balance the risk of suicidal thoughts or behaviors with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Should suicidal thoughts and behavior emerge during treatment, consider whether the emergence of these symptoms in any given patient may be related to the illness being treated.

Neurological Adverse Reactions

Somnolence and Fatigue

BRIVARACETAM causes dose-dependent increases in somnolence and fatigue-related adverse reactions (fatigue, asthenia, malaise, hypersomnia, sedation, and lethargy). In the Phase 3 controlled adjunctive epilepsy trials, these events were reported in 25% of patients randomized to receive BRIVARACETAM at least 50 mg/day (20% at 50 mg/day, 26% at 100 mg/day, and 27% at 200 mg/day) compared to 14% of patients who received placebo. The risk is greatest early in treatment but can occur at any time.

Dizziness and Disturbance in Gait and Coordination

BRIVARACETAM causes adverse reactions related to dizziness and disturbance in gait and coordination (dizziness, vertigo, balance disorder, ataxia, nystagmus, gait disturbance, and abnormal coordination). In the Phase 3 controlled adjunctive epilepsy trials, these events were reported in 16% of patients randomized to receive BRIVARACETAM at least 50 mg/day compared to 10% of patients who received placebo. The risk is greatest early in treatment but can occur at any time.

Psychiatric Adverse Reactions

BRIVARACETAM causes psychiatric adverse reactions. In the Phase 3 controlled adjunctive epilepsy trials, psychiatric adverse reactions were reported in approximately 13% of patients who received BRIVARACETAM (at least 50 mg/day) compared to 8% of patients who received placebo. Psychiatric events included both non-psychotic symptoms (irritability, anxiety, nervousness, aggression, belligerence, anger, agitation, restlessness, depression, depressed mood, tearfulness, apathy, altered mood, mood swings, affect lability, psychomotor hyperactivity, abnormal behavior, and adjustment disorder) and psychotic symptoms (psychotic disorder along with hallucination, paranoia, acute psychosis, and psychotic behavior). A total of 1.7% of adult patients treated with BRIVARACETAM discontinued treatment because of psychiatric reactions compared to 1.3% of patients who received placebo.

Hypersensitivity: Bronchospasm and Angioedema

BRIVARACETAM can cause hypersensitivity reactions. Bronchospasm and angioedema have been reported in patients taking BRIVARACETAM. If a patient develops hypersensitivity reactions after treatment with BRIVARACETAM, the drug should be discontinued. BRIVARACETAM is contraindicated in patients with a prior hypersensitivity reaction to BRIVARACETAM or any of the inactive ingredients.

Withdrawal of Antiepileptic Drugs

As with most antiepileptic drugs, BRIVARACETAM should generally be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus. But if withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.

4.5 Drugs interactions

Rifampin

Co-administration with rifampin decreases BRIVARACETAM plasma concentrations likely because of CYP2C19 induction. Prescribers should increase the BRIVARACETAM dose by up to 100% (i.e., double the dosage) in patients while receiving concomitant treatment with rifampin.

Carbamazepine

Co-administration with carbamazepine may increase exposure to carbamazepine-epoxide, the active metabolite of carbamazepine. Though available data did not reveal any safety concerns, if tolerability issues arise when co-administered, carbamazepine dose reduction should be considered.

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.

4.6 Use in special populations

Pregnancy

Risk Summary There are no adequate data on the developmental risks associated with use of BRIVARACETAM in pregnant women. In animal studies, BRIVARACETAM produced evidence of developmental toxicity (increased embryo fetal mortality and decreased fetal body weights in rabbits; decreased growth, delayed sexual maturation, and long-term neurobehavioral changes in rat offspring) at maternal plasma exposures greater than clinical exposures.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Data

Animal Data

Oral administration of BRIVARACETAM (0, 150, 300, or 600mg/kg/day) to pregnant rats during the period of organogenesis did not produce any significant maternal or embryo fetal toxicity. The highest dose tested was associated with maternal plasma exposures (AUC) approximately 30 times exposures in humans at the maximum recommended dose (MRD) of 200 mg/day.

Oral administration of BRIVARACETAM (0, 30, 60, 120, or 240 mg/kg/day) to pregnant rabbits during the period of organogenesis resulted in embryo fetal mortality and decreased fetal body weights at the highest dose tested, which was also maternally toxic. The highest no-effect dose (120 mg/kg/day) was associated with maternal plasma exposures approximately 4 times human exposures at the MRD.
When BRIVARACETAM (0, 150, 300, or 600 mg/kg/day) was orally administered to rats throughout pregnancy and lactation, decreased growth, delayed sexual maturation (female), and long-term neurobehavioral changes were observed in the offspring at the highest dose. The highest no-effect dose (300 mg/kg/day) was associated with maternal plasma exposures approximately 7 times human exposures at the MRD.
BRIVARACETAM was shown to readily cross the placenta in pregnant rats after a single oral (5 mg/kg) dose of ^{14}C-BRIVARACETAM. From 1 hour post dose, radioactivity levels in foetuses, amniotic fluid, and placenta were similar to those measured in maternal blood.

Lactation

Risk Summary
No data are available regarding the presence of BRIVARACETAM inhuman milk, the effects on the breastfed infant, or the effects of the drug on milk production. Studies in lactating rats have shown excretion of BRIVARACETAM or metabolites in milk.
The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for BRIVARACETAM and any potential adverse effects on the breastfed infant from BRIVARACETAM or from the underlying maternal condition.
Data
Animal Data
Following a single oral (5 mg/kg) dose of ^{14}C-BRIVARACETAM to lactating rats, radioactivity was secreted in milk and rapidly reached levels similar to those in plasma.

Geriatric Use

There were insufficient numbers of patients 65 years of age and older in the double-blind, placebo-controlled epilepsy trials (n=38) to allow adequate assessment of the effectiveness of BRIVARACETAM in this population. In general, dose selection for an elderly patient should be judicious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Renal Impairment

Dose adjustments are not required for patients with impaired renal function. There are no data in patients with end-stage renal disease undergoing dialysis, and use of BRIVARACETAM is not recommended in this patient population.

Hepatic Impairment

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

4.7 Effects on ability to drive and use machines

BRIVARACETAM causes somnolence, fatigue, dizziness, and disturbance in coordination. Patients should be monitored for these signs and symptoms and advised not to drive or operate

machinery until they have gained sufficient experience on BRIVARACETAM to gauge whether it adversely affects their ability to drive or operate machinery.

4.8 Undesirable effects

The following serious adverse reactions are described elsewhere in labeling:
Suicidal Behavior and Ideation
Neurological Adverse Reactions
Psychiatric Adverse Reactions
Hypersensitivity: Bronchospasm and Angioedema
Withdrawal of Antiepileptic Drugs

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.
In all controlled and uncontrolled trials performed in adult epilepsy patients, BRIVARACETAM was administered as adjunctive therapy to 2437 patients. Of these patients, 1929 were treated for at least 6 months, 1500 for at least 12 months, 1056 for at least 24 months, and 758 for at least 36 months. A total of 1558 patients (1099 patients treated with BRIVARACETAM and 459 patients treated with placebo) constituted the safety population in the pooled analysis of Phase 3 placebo-controlled studies in patients with partial-onset seizures. The adverse reactions presented in Table 2 are based on this safety population; the median length of treatment in these studies was 12 weeks. Of the patients in those studies, approximately 51% were male, 74% were Caucasian, and the mean age was 38 years.

In the Phase 3 controlled epilepsy studies, adverse events occurred in 68% of patients treated with BRIVARACETAM and 62% treated with placebo. The most common adverse reactions occurring at a frequency of at least 5% in patients treated with BRIVARACETAM doses of at least 50 mg/day and greater than placebo were somnolence and sedation (16%), dizziness (12%), fatigue (9%), and nausea and vomiting symptoms (5%).
The discontinuation rates due to adverse events were 5%, 8%, and 7% for patients randomized to receive BRIVARACETAM at the recommended doses of 50 mg, 100 mg, and 200 mg/day, respectively, compared to 4% in patients randomized to receive placebo.
Table 3 lists adverse reactions for BRIVARACETAM that occurred at least 2% more frequently for BRIVARACETAM doses of at least 50 mg/day than placebo.

Adverse Reactions in Pooled Placebo-Controlled Adjunctive Therapy Studies in Adult Patients with Partial-Onset Seizures (BRIVARACETAM 50 mg/day, 100 mg/day, and 200 mg/day)

Adverse Reactions	BRIVARACETAM (N=803) %	Placebo (N=459) %
Gastrointestinal disorders		
Nausea/vomiting symptoms	5	3
Constipation	2	0

Nervous system disorders		
Somnolence and sedation	16	8
Dizziness	12	7
Fatigue	9	4
Cerebellar coordination and balance disturbances*	3	1
Psychiatric disorders		
Irritability	3	1

* Cerebellar coordination and balance disturbances includes ataxia, balance disorder, coordination abnormal, and nystagmus.

There was no apparent dose-dependent increase in adverse reactions listed in Table 3 with the exception of somnolence and sedation.

Hematologic Abnormalities

BRIVARACETAM can cause hematologic abnormalities. In the Phase 3 controlled adjunctive epilepsy studies, a total of 1.8% of BRIVARACETAM -treated patients and 1.1% of placebo-treated patients had at least one clinically significant decreased white blood cell count ($<3.0x10^9$/L), and 0.3% of BRIVARACETAM treated patients and 0% of placebo treated patients had at least one clinically significant decreased neutrophil count ($<1.0\ x10^9$/L).

Comparison by Sex

There were no significant differences by sex in the incidence of adverse reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

4.9 Overdose

There is limited clinical experience with BRIVARACETAM overdose in humans. Somnolence and dizziness were reported in a patient taking a single dose of 1400 mg (14 times the highest recommended single dose) of BRIVARACETAM. The following adverse reactions were reported with BRIVARACETAM overdose: vertigo, balance disorder, fatigue, nausea, diplopia, anxiety, and bradycardia. In general, the adverse reactions associated with BRIVARACETAM overdose were consistent with the known adverse reactions.

There is no specific antidote for overdose with BRIVARACETAM. In the event of overdose, standard medical practice for the management of any overdose should be used. An adequate airway, oxygenation, and ventilation should be ensured; monitoring of cardiac rate and rhythm and vital signs is recommended. A certified poison control center should be contacted for updated information on the management of overdose with BRIVARACETAM. There are no

data on the removal of BRIVARACETAM using hemodialysis, but because less than 10% of BRIVARACETAM is excreted in urine, hemodialysis is not expected to enhance BRIVARACETAM clearance.

5. Pharmacological properties

5.1 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.

5.2 Pharmacodynamic properties

Interactions with Alcohol

In a pharmacokinetic and pharmacodynamics interaction study in healthy subjects, co-administration of BRIVARACETAM (single dose 200 mg [2 times greater than the highest recommended single dose]) and ethanol (continuous intravenous infusion to achieve a blood alcohol concentration of 60 mg/100 mL during 5 hours) increased the effects of alcohol on psychomotor function, attention, and memory. Co-administration of BRIVARACETAM and ethanol caused a larger decrease from baseline in saccadic peak velocity, smooth pursuit, adaptive tracking performance, and Visual Analog Scale (VAS) alertness, and a larger increase from baseline in body sway and in saccadic reaction time compared with BRIVARACETAM alone or ethanol alone. The immediate word recall scores were generally lower for BRIVARACETAM when co-administered with ethanol.

Cardiac Electrophysiology

At a dose 4 times the maximum recommended dose, BRIVARACETAM did not prolong the QT interval to a clinically relevant extent.

5.3 Pharmacokinetic properties

BRIVARACETAM tablets, oral solution, and injection can be used interchangeably. BRIVARACETAM exhibits linear and time-independent pharmacokinetics at the approved doses.

The pharmacokinetics of BRIVARACETAM are similar when used as monotherapy or as adjunctive therapy for the treatment of partial onset seizures.

Absorption

BRIVARACETAM is highly permeable and is rapidly and almost completely absorbed after oral administration. Pharmacokinetics is dose-proportional from 10 to 600 mg (a range that extends beyond the minimum and maximum single-administration dose levels described in Dosage and Administration. The median Tmax for tablets taken without food is 1 hour (range 0.25 to 3 hours). Co-administration with a high-fat meal slowed absorption, but the extent of absorption remained unchanged. Specifically, when a 50 mg tablet was administered with a high-fat meal, Cmax (maximum BRIVARACETAM plasma concentration during a dose interval, an exposure metric) was decreased by 37% and Tmax was delayed by 3 hours, but AUC (area under the BRIVARACETAM plasma concentration versus time curve, an exposure metric) was essentially unchanged (decreased by 5%).

Distribution

BRIVARACETAM is weakly bound to plasma proteins (≤20%). The volume of distribution is 0.5 L/kg, a value close to that of the total body water. BRIVARACETAM is rapidly and evenly distributed in most tissues.

Elimination

Metabolism

BRIVARACETAM is primarily metabolized by hydrolysis of the amide moiety to form the corresponding carboxylic acid metabolite, and secondarily by hydroxylation on the propyl side chain to form the hydroxy metabolite. The hydrolysis reaction is mediated by hepatic and extra-hepatic amidase. The hydroxylation pathway is mediated primarily by CYP2C19. In human subjects possessing genetic variations in CYP2C19, production of the hydroxy metabolite is decreased 2-fold or 10-fold, while the blood level of BRIVARACETAM itself is increased by 22% or 42%, respectively, in individuals with one or both mutated alleles. CYP2C19 poor metabolizers and patients using inhibitors of CYP2C19 may require dose reduction. An additional hydroxy acid metabolite is created by hydrolysis of the amide moiety on the hydroxyl metabolite or hydroxylation of the propyl side chain on the carboxylic acid metabolite (mainly by CYP2C9). None of the 3 metabolites are pharmacologically active.

Excretion

BRIVARACETAM is eliminated primarily by metabolism and by excretion in the urine. More than 95% of the dose, including metabolites, is excreted in the urine within 72 hours after intake. Fecal excretion accounts for less than 1% of the dose. Less than 10% of the dose is excreted unchanged in the urine. Thirty-four percent of the dose is excreted as the carboxylic acid metabolite in urine. The terminal plasma half-life (t1/2) is approximately 9 hours.

Specific Populations

Age

Pediatric Patients: An open-label, single-arm, multicenter, pharmacokinetic study with a 3-week evaluation period and fixed 3 step up-titration using BRIVARACETAM oral solution was conducted in 59 pediatric patients 4 years to less than 16 years of age. In those patients, plasma concentrations were shown to be dose-proportional. A weight-based dosing regimen is necessary to achieve BRIVARACETAM exposures in pediatric patients 4 years to less than 16 years of age that are similar to those observed in adults treated at effectives doses of BRIVARACETAM. The estimated plasma clearance was 1.61 L/h; 2.18 L/h; 3.19 L/h for pediatric patients weighing 20 kg, 30 kg, and 50 kg, respectively. In comparison, plasma clearance was estimated at 3.58 L/h in adult patients (70 kg body weight).

Geriatric Population: In a study in elderly subjects (65 to 79 years old; creatinine clearance 53 to 98 mL/min/1.73 m^2) receiving BRIVARACETAM 200 mg twice daily (2 times the highest recommended dosage), the plasma half-life of BRIVARACETAM was 7.9 hours and 9.3 hours in the 65 to 75 and >75 years groups, respectively. The steady-state plasma clearance of BRIVARACETAM was slightly lower (0.76 mL/min/kg) than in young healthy controls (0.83 mL/min/kg).

Sex

There were no differences observed in the pharmacokinetics of BRIVARACETAM between male and female subjects.

Race/Ethnicity

A population pharmacokinetic analysis comparing Caucasian and non-Caucasian patients showed no significant pharmacokinetic difference.

Renal Impairment

A study in adult subjects with severe renal impairment (creatinine clearance<30 mL/min/1.73m² and not requiring dialysis) revealed that the plasma AUC of BRIVARACETAM was moderately increased (21%) relative to healthy controls, while the AUCs of the acid, hydroxy, and hydroxyl acid metabolites were increased 3-fold, 4-fold, and 21-fold, respectively. The renal clearance of these inactive metabolites was decreased10-fold. BRIVARACETAM has not been studied in patients undergoing hemodialysis.

Hepatic Impairment

A pharmacokinetic study in adult subjects with hepatic cirrhosis, Child-Pugh grades A, B, and C, showed 50%, 57%, and 59% increases in BRIVARACETAM exposure, respectively, compared to matched healthy controls. The effect of hepatic impairment on BRIVARACETAM pharmacokinetics in pediatric patients is expected to be comparable to the effect observed in adults.

6. Nonclinical properties

6.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

In a carcinogenicity study in mice, oral administration of BRIVARACETAM (0, 400, 550, or 700 mg/kg/day) for 104 weeks increased the incidence of liver tumors (hepatocellular adenoma and carcinoma) in male mice at the two highest doses tested. At the dose (400 mg/kg) not associated with an increase in liver tumors, plasma exposures (AUC) were approximately equal to those in humans at the maximum recommended dose (MRD) of 200 mg/day. Oral administration (0, 150, 230, 450, or 700 mg/kg/day) to rats for 104 weeks resulted in an increased incidence of thymus tumors (benign thymoma) in female rats at the highest dose tested. At the highest dose not associated with an increase in thymus tumors, plasma exposures were approximately 9 times those in humans at the MRD.

Mutagenesis

BRIVARACETAM was negative for genotoxicity in *in vitro* (Ames, mouse lymphoma, and CHO chromosomal aberration) and *in vivo* (rat bone marrow micronucleus) assays.

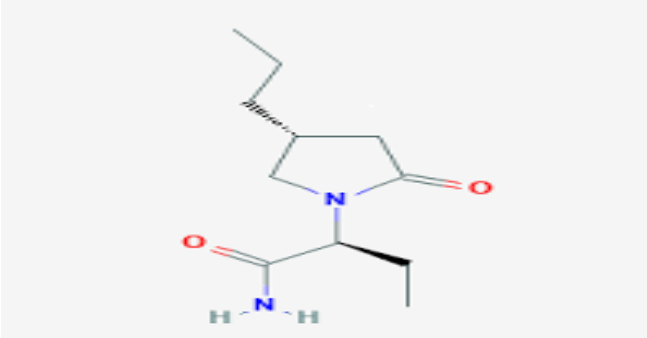
Impairment of Fertility

Oral administration of BRIVARACETAM (0, 100, 200, or 400 mg/kg/day) to male and female rats prior to and throughout mating and early gestation produced no adverse effects on fertility. The highest dose tested was associated with plasma exposures approximately 6 (males) and 13 (females) times those in humans at the MRD.

7. Description

BRIVARACETAM

BRIVARACETAM is (2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl]butanamide. The empirical formula is $C_{11}H_{20}N_2O_2$ and its molecular weight is 212.29 g/mol. The chemical structure of BRIVARACETAM is:



BRIVARACETAM Oral Solution is slightly viscous, clear, colourless to pale yellowish liquid.

The excipients used are Sucralose, Sorbitol, Glycerin, Propylene glycol, Peppermint supreme & Raspberry Classic.

8. Pharmaceutical particulars

8.1 Incompatibilities

None stated

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

BRIVARACETAM is available in bottle of 100ml.

8.4 Storage and handing instructions

- Store at room temperature, protected from light and moisture.
- Keep all medicines out of reach of children.

9. Patient counselling information

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Dosage will be as directed by the Physician
- Keep all medicines out of reach of children
- If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

9.1.What BRITZILAM is and what it is used for

9.2.What you need to know before you take BRITZILAM

9.3.How to take BRITZILAM

9.4.Possible side effects

9.5.How to store BRITZILAM

9.6.Contents of the pack and other information

9.1 What BRITZILAM is and what it is used for

BRITZILAM is indicated as adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy.

9.2 What you need to know before you take BRITZILAM

Do not take BRITZILAM

- If you are allergic to BRIVARACETAM or any of the inactive ingredients of this medicine.

Warnings and precautions

- Talk to your doctor before taking BRITZILAM
- When treating a pregnant woman with BRITZILAM, the physician should carefully consider both the potential risks, along with the established benefits. This decision can only be made on a case by case basis.
- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.

Infants

- Safety and efficacy in Pediatric patients have not been established.

Other medicines and BRITZILAM

- Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

Pregnancy and breast-feeding

- If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

- Patients should be cautioned about the potential risk of somnolence, fatigue, dizziness, and disturbance in coordination which influence on their ability to drive a car and operate machinery.

9.3 How to take BRITZILAM

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

BRITZILAM Tablets should be administered orally with food to enhance absorption.

If you took more BRITZILAM tablets than you should contact your doctor. Your doctor will establish the best possible treatment of overdose.

The possible side effects of an overdose of BRITZILAM are vertigo, balance disorder, fatigue, nausea, diplopia, anxiety, and bradycardia.

If you forget to take BRITZILAM:

Contact your doctor if you have missed one or more doses.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking BRITZILAM

Should your doctor decide to stop your BRITZILAM treatment, he/she will instruct you about the gradual withdrawal of BRITZILAM.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

9.4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately or contact the casualty department at your nearest hospital, if you get any of the following serious side effects:

- Bronchospasm and Angioedema
- Nausea/vomiting symptoms
- Somnolence and sedation
- Irritability

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: http://www.torrentpharma.com/index.php/site/info/adverse_event_reporting. By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store BRITZILAM

Store at room temperature, protected from light and moisture.

Keep all medicines out of reach of children

9.6 Contents of the pack and other information

What BRITZILAM contains
The active substance in BRITZILAM is BRIVARACETAM.
The excipients used are Sucralose, Sorbitol, Glycerin, Propylene glycol, Peppermint supreme & Raspberry Classic.

BRITZILAM is available in bottle of 100ml.

10. Details of manufacturer

Manufactured By:

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

11. Details of permission or licence number with date

Mfg Lic No. TS/MDL/2019-47327 issued on 03.03.2021

12. Date of revision

Not Applicable

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/ BRITZILAM 10mg/mL /APR-21/01/PI