Brivanext ब्रिवानेक्सट
Brivaracetam Tablets 10/25/50/75/100 mg

To be sold by retail on the prescription of a RMP only

PRESCRIBING INFORMATION

1. GENERIC NAME

Brivaracetam Tablets 10 mg
Brivaracetam Tablets 25 mg
Brivaracetam Tablets 50 mg
Brivaracetam Tablets 75 mg
Brivaracetam Tablets 100 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Brivaracetam Tablets 10 mg
Each film coated tablet contains
Brivaracetam-----10 mg
Colors : Titanium Dioxide IP

Brivaracetam Tablets 25 mg
Each film coated tablet contains
Brivaracetam-----25 mg
Colors : Titanium Dioxide IP
Ferric Oxide Red USP-NF

Brivaracetam Tablets 50 mg
Each film coated tablet contains
Brivaracetam….. 50 mg
Colors : Titanium Dioxide IP
Ferric Oxide Yellow USP-NF

Brivaracetam Tablets 75 mg
Each film coated tablet contains
Brivaracetam ….. 75 mg
Colors : Titanium Dioxide IP
Ferric Oxide Red USP-NF
Ferrosoferric Oxide USP-NF

Brivaracetam Tablets 100 mg
Each film coated tablet contains
Brivaracetam-----100 mg
Colours : Titanium Dioxide IP
FD&C Yellow and Sunset Yellow FCF

3. DOSAGE FORM AND STRENGTH

Brivaracetam is available as film coated tablets 10 mg, 25 mg, 50 mg, 75 mg and 100 mg.

4. CLINICAL PARTICULARS

4.1. Indications

Brivaracetam tablets are indicated as an 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

Dosage Information

Monotherapy or Adjunctive Therapy

When initiating treatment, gradual dose escalation is not required. Dosage should be adjusted based on clinical response and tolerability.

Table 1: Recommended Dosage for Adults

Age	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)

Administration Instructions for Brivaracetam Tablets

Brivaracetam tablets should be swallowed whole with liquid. Brivaracetam tablets should not be chewed or crushed.

Discontinuation of Brivaracetam

Avoid abrupt withdrawal from Brivaracetam in order to minimize the risk of increased seizure frequency and status epilepticus.

Patients with Hepatic Impairment

For all stages of hepatic impairment, the recommended starting dosage for adults is 25 mg twice daily (50 mg per day), and the recommended maximum dosage is 75 mg twice daily (150 mg per day).

Co-administration with Rifampin

Increase the Brivaracetam dosage in patients on concomitant rifampin by up to 100% (i.e., double the dosage).

4.3. Contraindications

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

4.4. Special Warnings and Precautions for Use

Suicidal Behaviour and Ideation

Antiepileptic drugs (AEDs), including Brivaracetam, increase the risk of suicidal thoughts or behaviour 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 behaviour, and/or any unusual changes in mood or behaviour.

The increased risk of suicidal thoughts or behaviour with AEDs was observed as early as one week after starting drug treatment with AEDs and persisted for the duration of treatment.

Anyone considering prescribing Brivaracetam or any other AED must balance the risk of suicidal thoughts or behaviours 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 behaviour. Should suicidal thoughts and behaviour 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

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.

Somnolence and Fatigue

Brivaracetam causes dose-dependent increases in somnolence and fatigue-related adverse reactions (fatigue, asthenia, malaise, hypersomnia, sedation, and lethargy. 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). The risk is greatest early in treatment but can occur at any time.

Psychiatric Adverse Reactions

Brivaracetam causes psychiatric adverse reactions. 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 behaviour, and adjustment disorder) and psychotic symptoms (psychotic disorder along with hallucination, paranoia, acute psychosis, and psychotic behaviour).

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. Drug 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.

Other enzyme inducers

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.

4.6. Use in Special Populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy

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 embryofetal 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.

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 embryofetal toxicity.

Oral administration of Brivaracetam (0, 30, 60, 120, or 240 mg/kg/day) to pregnant rabbits during the period of organogenesis resulted in embryofetal mortality and decreased fetal body weights at the highest dose tested, which was also maternally toxic. 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.

Brivaracetam was shown to readily cross the placenta in pregnant rats after a single oral (5 mg/kg) dose of ^{14}C-brivaracetam. *[Reference: BRIVIACT US FDA Label. Dated: May 2018].*

Lactation

No data are available regarding the presence of Brivaracetam in human 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 breast fed infant from Brivaracetam or from the underlying maternal condition. 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 *[Reference: BRIVIACT US FDA Label. Dated: May-2018].*

Pediatric Use

Safety and effectiveness of Brivaracetam tablets has not been established in pediatric patients 4 years to less than 16 years of age

Geriatric Use

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

DRUG ABUSE AND DEPENDENCE

Abuse

Brivaracetam at the recommended single dose (50 mg) caused fewer sedative and euphoric effects than alprazolam; however, Brivaracetam at supratherapeutic single doses (200mg and 1000 mg) was similar to alprazolam on other measures of abuse.

Dependence

There was no evidence of physical dependence potential or a withdrawal syndrome with Brivaracetam.

4.7. Effects on Ability to Drive and Use Machines

Brivaracetam has minor or moderate influence on the ability to drive and use machines.

Due to possible differences in individual sensitivity some patients might experience somnolence, dizziness, and other central nervous system (CNS) related symptoms. Patients should be advised not to drive a car or to operate other potentially hazardous machines until they are familiar with the effects of Brivaracetam on their ability to perform such activities.

4.8. Undesirable Effects

Adverse reactions are listed by System Organ Class (SOC) and within each frequency grouping [Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000)] the adverse reactions are presented in order of decreasing seriousness.

System organ class	Frequency	Adverse reactions from clinical trials
Infections and infestations	Common	Influenza
Blood and lymphatic system disorders	Uncommon	Neutropenia
Metabolism and nutrition disorders	Common	Decreased appetite
Immune system disorders	Uncommon	Type I hypersensitivity
Psychiatric disorders	Common	Depression, anxiety, insomnia, irritability
	Uncommon	Suicidal ideation, psychotic disorder, aggression, agitation
Nervous system disorders	Very common	Dizziness, somnolence
	Common	Convulsion, vertigo
Respiratory, thoracic and mediastinal disorders	Common	Upper respiratory tract infections, cough
Gastrointestinal disorders	Common	Nausea, vomiting, constipation
General disorders and administration site conditions	Common	Fatigue

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. To report Suspected Adverse Reactions, contact MSN Laboratories Private Limited at pharmacovigilance@msnlabs.com or through company website www.msnlabs.com->Contact us->Medical Enquiry/ to report a side effect.

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. 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 protein 2A (SV2A) in the brain, which may contribute to the anticonvulsant effect.

5.2 Pharmacodynamic Properties

Interaction with Alcohol

In a pharmacokinetic and pharmacodynamic 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 *[Reference: BRIVIACT US FDA Label. Dated: May 2018].*

5.3 PHARMACOKINETIC PROPERTIES

Brivaracetam exhibits linear and time-independent pharmacokinetics at the approved doses.

The pharmacokinetics of Brivaracetam is 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. The median T_{max} 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, C_{max} (maximum Brivaracetam plasma concentration during a dose interval, an exposure metric) was decreased by 37% and T_{max} 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 hydroxy 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 ($t_{1/2}$) is approximately 9 hours.

Specific Populations

Age:

Pediatric Patients: Brivaracetam 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. 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: 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

No significant pharmacokinetic difference was showed in Caucasian and non-Caucasian patients.

Renal Impairment

In patients with severe renal impairment (creatinine clearance<30 mL/min/1.73m² and not requiring dialysis) the plasma AUC of Brivaracetam was moderately increased (21%), while the AUCs of the acid, hydroxy and hydroxyacidmetaboliteswereincreased3-fold,4-fold,and21-fold,respectively.Therenal clearance of these inactive metabolites was decreased10-fold. Brivaracetam has not been studied in patients undergoing hemodialysis.

Hepatic Impairment

In patients with hepatic cirrhosis, Child-Pugh grades A, B, and C, showed 50%, 57%, and 59% increases in Brivaracetam exposure, respectively.

Drug Interaction Studies

In Vitro Assessment of Drug Interactions

Drug-Metabolizing Enzyme Inhibition

Brivaracetam did not inhibit CYP1A2, 2A6, 2B6, 2C8, 2C9, 2D6, or 3A4. Brivaracetam weakly inhibited CYP2C19 and would not be expected to cause significant inhibition of CYP2C19 in humans. Brivaracetam was an inhibitor of epoxide hydrolase, (IC50 = 8.2 μM), suggesting that Brivaracetam can inhibit the enzyme *in vivo*.

Drug-Metabolizing Enzyme Induction

Brivaracetam at concentrations up to 10 μM caused little or no change of mRNA expression of CYP1A2, 2B6, 2C9, 2C19, 3A4, and epoxide hydrolase. It is unlikely that Brivaracetam will induce these enzymes *in vivo*.

Transporters

Brivaracetam was not a substrate of P-gp, MRP1, or MRP2. Brivaracetam did not inhibit or weakly inhibit BCRP, BSEP, MATE1, MATE2/K, MRP2, OAT1, OAT3, OCT1, OCT2, OATP1B1, OATP1B3, or P-gp, suggesting that Brivaracetam is unlikely to inhibit these transporters *in vivo.*

In Vivo Assessment of Drug Interactions

Drug Interaction Studies with Antiepileptic Drugs (AEDs)

The in vivo drug interactions are listed in below table.

Concomitant AED	Influence of AED on Brivaracetam	Influence of Brivaracetam on AED
Carbamazepine	26% decrease in plasma concentration	None for carbamazepine Increase of carbamazepine-epoxide metabolite*
Lacosamide	No data	None
Lamotrigine	None	None
Levetiracetam	None	None
Oxcarbazepine	None	None on the active monohydroxy metabolite derivative (MHD)
Phenobarbital	19% decrease in plasma concentration	None
Phenytoin	21% decrease in plasma concentration	Up to 20% increase in plasma concentration**
Pregabalin	No data	None
Topiramate	None	None
Valproic acid	None	None
Zonisamide	No data	None

* *Brivaracetam is a reversible inhibitor of epoxide hydrolase resulting in an increased concentration of carbamazepine epoxide, an active metabolite of carbamazepine. The carbamazepine epoxide plasma concentration increased up to 198% at a Brivaracetam dose of 100 mg twice daily.*

** *At a supratherapeutic dose of 400 mg/day brivaracetam, there was a 20% increase in phenytoin plasma concentration.*

Drug Interaction Studies with Other Drugs

Effect of Other Drugs on Brivaracetam

Co-administration with CYP inhibitors or transporter inhibitors is unlikely to significantly affect Brivaracetam exposure. Co-administration with rifampin decreases brivaracetam plasma concentrations by 45%, an effect that is probably the result of CYP2C19 induction.

Oral Contraceptives

Co-administration of Brivaracetam 200 mg twice daily (twice the recommended maximum daily dosage) with an oral contraceptive containing ethinylestradiol (0.03 mg) and levonorgestrel (0.15 mg) reduced estrogen and progestin AUCs by 27% and 23%, respectively, without impact on suppression of ovulation. However, co-administration of Brivaracetam 50 mg twice daily with an oral contraceptive containing ethinylestradiol (0.03 mg) and levonorgestrel (0.15 mg) did not significantly influence the pharmacokinetics of either substance. The interaction is not expected to be of clinical significance.

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 *[Reference: BRIVIACT US FDA Label. Dated: May-2018].*

7. PHARMACEUTICAL PARTICULARS

7.1 Incompatibilities

None

7.2 Packing Information

10's Alu-Alu.

7.3 Storage and Handling Instructions

Store at a temperature not exceeding 30°C, protected from light and moisture

8. PATIENT COUNSELING INFORMATION

Advise the patient to read package insert.

Suicidal Behavior and Ideation

Counsel patients, their caregivers, and/or families that antiepileptic drugs, including Brivaracetam, may increase the risk of suicidal thoughts and behavior, and advise patients to be alert for the emergence or worsening of symptoms of depression; unusual changes in mood or behavior or suicidal thoughts, behavior, or thoughts about self-harm. Advise patients, their care givers and/or families to report behaviors of concern immediately to a healthcare provider.

Neurological Adverse Reactions

Counsel patients that Brivaracetam causes somnolence, fatigue, dizziness, and gait disturbance. These adverse reactions, if observed, are more likely to occur early in treatment but can occur at any time. Advise patients 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.

Psychiatric Adverse Reactions

Advise patients that Brivaracetam causes changes in behavior (e.g., aggression, agitation, anger, anxiety, and irritability) and psychotic symptoms. Instruct patients to report these symptoms immediately to their healthcare provider.

Hypersensitivity: Bronchospasm and Angioedema

Advise patients that symptoms of hypersensitivity including bronchospasm and angioedema can occur with Brivaracetam. Instruct them to seek immediate medical care should they experience signs and symptoms of hypersensitivity.

Withdrawal of Antiepileptic Drugs

Advise patients not to discontinue use of Brivaracetam without consulting with their healthcare provider. Brivaracetam should normally be gradually withdrawn to reduce the potential for increased seizure frequency and status epilepticus.

Pregnancy

Advice patients to notify their health care provider if they become pregnant or intend to become pregnant during Brivaracetam therapy.

Dosing Instructions

Counsel patients that Brivaracetam may be taken with or without food. Instruct patients that Brivaracetam tablets should be swallowed whole with liquid and not chewed or crushed.

9. DETAILS OF MANUFACTURER

MSN Laboratories Private Limited,
(Formulations Division),
Plot No. 42, Anrich Industrial Estate,
Bollaram, Sangareddy District - 502 325,
Telangana, India.

10. DETAILS OF MANUFACTURING LICENCE NUMBER

38/MD/AP/2007/F/CC

11. DATE OF REVISION

March 2021

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