

## Prescribing Information for Brivaracetam<sup>1</sup> as adjunct therapy in the treatment of partial-onset seizures with or without secondary generalization, in adult and adolescent patients from 16 years of age with epilepsy.

### Licensed Indication

Epilepsy in adults and adolescent patients from 16 years of age

### Dosage and administration

Available as 10mg, 25mg, 50mg, 75mg and 100mg tablets and a 10mg/ml oral solution

*Adult:* 50-100mg daily in two divided doses (morning and evening) titrated to response and tolerability. Maximum 200mg/day

*Elderly:* No dose adjustment is needed in elderly patients.

*Renal Impairment:* No dose adjustment is needed in patients with impaired renal function. Not recommended in end-stage renal disease patients undergoing dialysis

*Hepatic Impairment:* Starting dose 50 mg/day (25mg BD), maximum daily dose of 150 mg (75mg BD) is recommended for all stages of hepatic impairment

Discontinuation: the dose should be reduced gradually by 50mg/day on a weekly basis down to 50mg (25mg BD). This should be maintained for 1 week then further reduced to 20mg/day (10mg BD) for 1 week before stopping.

### Adverse effects, Precautions and Contra-indications<sup>1</sup>

#### Contraindications

Known hypersensitivity to brivaracetam, other pyrrolidone derivatives or any of the excipients.

#### Special Precautions

Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic drugs (AEDs). Patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should any signs of suicidal ideation or behaviour emerge.

Dose adjustments are recommended for patients with hepatic impairment

Lactose intolerance – tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

#### Adverse Effects

The most frequently reported adverse reactions with treatment were: somnolence and dizziness of mild to moderate intensity. Somnolence and fatigue were reported with increasing dose.

The adverse reactions most frequently resulting in discontinuation of therapy were dizziness and convulsion.

See SPC for full list of adverse effects <https://www.medicines.org.uk/emc/>

<https://www.medicines.org.uk/emc/medicine/31452> (tablets) <https://www.medicines.org.uk/emc/medicine/31453> (syrup)

### Drug Interactions

See product SPC for full list of drug interactions <https://www.medicines.org.uk/emc/>  
<https://www.medicines.org.uk/emc/medicine/31452> (tablets) <https://www.medicines.org.uk/emc/medicine/31453> (syrup)

or the British National Formulary ( [www.bnf.org](http://www.bnf.org) )

## Communication

Brivaracetam has been approved for use in patients who responded to but were unable to tolerate levetiracetam.

Brivaracetam should be initiated and stabilised by the epilepsy specialist before the GP is asked to prescribe.

Secondary care will review initially after 3 months then following stabilisation 6-12 months.

**This information is not inclusive of all prescribing information, potential adverse effects and drug interactions. Please refer to full prescribing data on SPC website ( <https://www.medicines.org.uk/emc/> ) or the British National Formulary ( [www.bnf.org](http://www.bnf.org) ).**

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<sup>1</sup>Brivaracetam – Summary of Product Characteristics. Available at <https://www.medicines.org.uk/emc/>