City Hospitals Sunderland NHS
NHS Foundation Trust

NHS
Sunderland
Clinical Commissioning Group

Information for primary care — Brivaracetam (Briviact®)

RAG Status – Green +

Background/Summary information

Brivaracetam has a high selectivity 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.

Related NICE guidance

Specific NICE guidance is not available, but guidance on Epilepsies: diagnosis and management, NICE CG137 (January 2012, last updated: February 2016 https://www.nice.org.uk/guidance/cg137) recommends that adjunctive or 'add-on' therapy should only be considered when attempts at monotherapy with AEDs have not resulted in seizure freedom.

See manufacturer's SPC (Briviact®) for full prescribing information)
Tablets: http://www.medicines.org.uk/emc/medicine/31452
Oral solution: http://www.medicines.org.uk/emc/medicine/31453
Solution for injection: http://www.medicines.org.uk/emc/medicine/31457

Licensed indication

Brivaracetam is licensed for adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalisation in adult and adolescent patients from 16 years of age with epilepsy.

Dosage and administration

Usual dose:
Initially 25–50 mg twice daily, adjusted according to response; usual maintenance 25–100 mg twice daily.

Key points for safe use:

- Manufacturer advises oral solution can be diluted in water or juice shortly before swallowing.
- Manufacturer advises if switching between oral therapy and intravenous therapy (for those temporarily unable to take oral medication), the total daily dose and the frequency of administration should be maintained. There is no experience with twice daily intravenous administration of brivaracetam for a period longer than four days.
- Manufacturer advises if one or more doses are missed, a single dose should be taken as soon as possible and the next dose should be taken at the usual time.

GP and specialist responsibilities

- Patient will be reviewed regularly by the specialist in secondary care until stable. Patient may then be transferred to GP care for monitoring.
- The GP will provide prescriptions for the patient in line with the instructions given by the specialist in secondary care.
- The specialist team will provide advice and answer queries on the use of this drug and can be contacted on 0191 565 6256.

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Contraindications
Hypersensitivity to the active substance or other pyrrolidone derivatives or to any of the excipients (see SPC). Brivaracetam tablets contain lactose. Patients with rare heriditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take the tablets.
Cautions
Suicidal ideation and behaviour have been reported in patients treated with anti-epileptic drugs (AEDs), including brivaracetam. There are limited clinical data on the use of brivaracetam in patients with pre-existing hepatic impairment; a maximum daily dose of 150 mg administered in 2 divided doses is recommended Pregnancy and breastfeeding: Manufacturer advises avoid unless potential benefit outweighs risk — no information available.
Side effects
Common or very common: Anxiety; constipation; decreased appetite; depression; dizziness; insomnia; irritability; malaise; nausea; somnolence; vertigo; vomiting **Uncommon:** Aggression; agitation; neutropenia; psychotic disorder; suicidal ideation
Drug interactions
There is no observed benefit if brivaracetam and levetiracetam are administered concurrently; additionally there are no known safety or tolerability concerns. Brivaracetam with alcohol is not recommended. Brivaracetam plasma concentration may be increased by strong CYP2C19 inhibitors e.g. fluvoxamine, fluconazole. Brivaracetam plasma concentration may be reduced by the following: • Rifampicin – prescribers should consider adjusting the dose of brivaracetam • St John's wort • Carbamazepine – no dose adjustment required • Phenobarbital – no dose adjustment required • Phenytoin – no dose adjustment required Brivaracetam may increase the plasma concentration of drugs metabolised by CYP2C19 e.g. lansoprazole, omeprazole and diazepam.
Monitoring
No specific monitoring of patients is required.
Cost
10 mg white tab, 14 = £34.64. 25 mg grey tab, 56 = £129.64. 50 mg yellow tab, 56 = £129.64. 75 mg purple tab, 56 = £129.64. 100 mg green tab, 56 = £129.64. 10 mg/mL oral solution, 300 mL = £115.83. 10 mg/mL solution for injection/infusion, 10 x 5 mL = £222.75.

References

1. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press <http://www.medicinescomplete.com> Accessed: 12/1/17
2. Briviact tablets SPC (updated: 22/5/15), Briviact oral solution SPC (updated: 21/1/16), Briviact injection SPC (updated: 22/1/16). electronic Medicines Compendium (eMC). http://www.medicines.org.uk/emc/. Accessed: 12/1/17