Zorginstituut Nederland

Brivaracetam (Briviact)

Summary of recommendations by *Zorginstituut Nederland* dated 23 May 2016

Zorginstituut Nederland has approved a pharmacotherapeutic report for the medicine brivaracetam (Briviact®), whereby they reached the following conclusion.
Based on the criteria of the Medicines Reimbursement System (GVS), the *Zorginstituut* is of the opinion that brivaracetam is mutually replaceable with levetiracetam and lacosamide, and can therefore be included on List 1A of the GVS in cluster 0N03AXDO V with a standard dose of 100 mg.

Background

In a letter dated 7 March 2016 (CIBG-16-01790), the Minister of Health, Public Welfare and Sport asked *Zorginstituut Nederland* to assess whether brivaracetam (Briviact®) is mutually replaceable with a drug that is included in the GVS system. They have now completed their assessment.

The manufacturer has asked that brivaracetam (Briviact®) is deemed mutually replaceable with lacosamide, perampanel and topiramate; he feels that it is not mutually replaceable with levetiracetam because the latter's field of indication focuses on monotherapy. If the current cluster classification remains unaltered, brivaracetam can be included both in cluster 0N03AXEO (perampanel, topiramate) and in cluster 0N03AXDO (levetiracetam, lacosamide) on List 1A of the Health Care Regulation (*Regeling zorgverzekering,* Rzv).

Brivaracetam has a high and selective affinity for the synaptic vesicle protein 2A (SV2A). The assumption is that binding to SV2A is the primary mechanism for the anticonvulsive effect of brivaracetam.
Brivaracetam is available as 25, 50, 75 and 100 mg film-coated tablets and as a 10 mg/ml oral solution.
It is registered as adjuvant therapy for the treatment of partial onset epilepsy with or without secondary generalisation in adults and adolescents from the age of 16 years. The initial dose is 50 or 100 mg per day divided over two equal doses, once in the morning and once in the evening. Depending on the individual response and tolerance, the dose can be adjusted to a maintenance dose of 50-200 mg/day.

Assessment of mutual replaceability

Based on the GVS criteria, brivaracetam (Briviact®) can be regarded as mutually

replaceable with levetiracetam and lacosamide, which have been placed together on List 1A of the GVS in cluster 0N03AXDO V.

***Zorginstituut Nederland*'s advice**

Based on the above grounds, *Zorginstituut Nederland* advises the Minister of Public Health, Welfare and Sport that brivaracetam can be included on List 1A of the Rvz in cluster 0N03AXDO V, with a standard dose of 100 mg.

For further information, please contact: JBoer@zinl.nl; warcg@zinl.nl

The original text of this advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.