



Daclizumab (Zinbryta®) for the treatment of relapsing (recidive) forms of multiple sclerosis (RMS)

Summary of recommendations by *Zorginstituut Nederland* dated 15 December 2016

Zorginstituut Nederland carried out a marginal assessment of the medicine daclizumab (Zinbryta®), whereby they came to the following conclusion.

Based on the criteria of the Medicines Reimbursement System (GVS), daclizumab is interchangeable with interferon beta products (interferon beta-1a, interferon beta-1b, peginterferon beta-1a) and glatiramer acetate (Copaxone), which are included in the GVS.

In a letter dated 17 October 2016 (CIBG-16-03127), the Minister of Health, Welfare and Sport asked *Zorginstituut Nederland* to perform a substantive assessment of whether the medicine daclizumab (Zinbryta®) is interchangeable with a drug currently included in the GVS. With the advice of the Scientific Advisory Board (WAR), the *Zorginstituut* has now completed its assessment.

Registered indication

Daclizumab is a humanised IgG1 monoclonal antibody, registered for adult patients for the treatment of relapsing (recidive) forms of multiple sclerosis (RMS).

Zinbryta® contains 150 mg daclizumab in 1-ml solution for injection in a pre-filled injection or pen. The recommended dose is once a month a subcutaneous 150-mg injection.

Conclusion on interchangeability

Based on current criteria, daclizumab (Zinbryta®) is interchangeable with the other medicines in GVS cluster 0L03ABBP, which includes: interferon beta products (interferon beta-1a, interferon beta-1b, peginterferon beta-1a).

Based on the assessment of glatiramer acetate in 2001, which was also confirmed by the recent assessment of alemtuzumab (Lemtrada®), glatiramer acetate (Copaxone®), which is still included on List 1B of the GVS, can also be added to this cluster.

Zorginstituut Nederland's advice

Zorginstituut Nederland advises the inclusion of daclizumab (Zinbryta®) on List 1A in cluster 0L03ABBP, which includes: interferon beta products (interferon beta-1a, interferon beta-1b, peginterferon beta-1a). Glatiramer acetate (Copaxone®), which is currently included on List 1B, can also be added to this cluster. The standard dose of daclizumab is 5 mg, the standard dose for glatiramer acetate is 20 mg.

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

The original text of this excerpt from 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.