



Cariprazine (Reagila®) for the treatment of schizophrenia

Package advice of *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 4 June 2018

Zorginstituut Nederland has issued package advice on the pharmaceutical cariprazine (Reagila®), whereby they came to the following conclusion.

In a letter dated 25 May 2018 (CIBG-18-06295), the Ministry of Health, Welfare and Sport (WVS) asked *Zorginstituut Nederland* to carry out a substantive assessment of the medicinal product Reagila® to determine whether it can be included in the Medicine Reimbursement System (GVS).

The Ministry requested a marginal assessment.

Reagila® is an atypical antipsychotic, registered for the treatment of schizophrenia in adult patients. It is available in hard capsules with cariprazine hydrochloride corresponding to 1.5 mg, 3 mg, 4.5 mg and 6 mg cariprazine.

Conclusion of the marginal assessment

Based on the criteria for interchangeability, the *Zorginstituut* concludes that Reagila® is interchangeable with drugs that are already included in cluster 4N05AEAO of the GVS. This cluster contains eight atypical antipsychotics: aripiprazole (Abilify®), lurasidone (Latuda®), olanzapine (Zyprexa®), paliperidone (Invega®), quetiapine (Seroquel®), risperidone (Risperdal®), sertindole (Serdolact®) and sulpiride.

A DDD of 3 mg has been established for cariprazine. This is within the dose range stated in the registration text for cariprazine. The standard dose can therefore be fixed at 3 mg.

Advice

We advise the Minister to include cariprazine (Reagila®) in List 1A of the GVS, in cluster 4N05AEAO. A standard dose of 3 mg can be established.

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 a 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.