

Brexpiprazole (Rxulti®) for the treatment of schizophrenia in adults

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 16 April 2019

Zorginstituut Nederland carried out a marginal assessment of the medicinal product brexpiprazole (Rxulti®), whereby the following conclusion was drawn.

In a letter dated 21 January 2019 (CIBG-19-07506), the Minister of Health, Welfare and Sport (VWS) asked the *Zorginstituut* to assess whether the product brexpiprazole (Rxulti®) can be accepted into the Medicine Reimbursement System (GVS). The Minister asked us to limit ourselves to a marginal assessment.

Brexpiprazole (Rxulti®), an antipsychotic, is registered and indicated for the treatment of schizophrenia in adults. Brexpiprazole is available as film-coated tablets in doses of 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg. The recommended dose is 2 to 4 mg once daily. The maximum daily dose is 4 mg.

Conclusion of the marginal assessment

Based on the criteria for interchangeability, we conclude that brexpiprazole (Rxulti®) is interchangeable with the other drugs in GVS cluster N405AXAO V, which includes: aripiprazole, cariprazine, paliperidone, quetiapine and risperidone."

The DDD for brexpiprazole was established by the World Health Organisation (WHO) at 3 mg. The DDD falls within the dose range stipulated in the registration text. The standard dose can therefore be fixed at 3 mg.

Advice

We advise the Minister to include brexpiprazole (Rxulti®) on List 1A in cluster N405AXAO V of the GVS. A standard dose of 3 mg can be established.

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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.