Zorginstituut Nederland

Safinamide (Xadago®)

Summary of recommendations by Zorginstituut Nederland dated 21 March 2016

Zorginstituut Nederland has approved a pharmacotherapeutic report for the medicine safinamide (Xadago®). They reached the following conclusion.
Based on the criteria of the Medicines Reimbursement System (GVS), safinamide can be included in the GVS on List 1A in cluster 0N04BDAO V, with a standard dose of 75 mg.

Background

In a letter dated 13 January 2016 (CIBG-16-1441), the Minister of Health, Public Welfare and Sport asked Zorginstituut Nederland to assess whether safinamide (Xadago®) is mutually replaceable with a drug that is included in the GVS system. Zorginstituut Nederland, advised by the Scientific Advisory Board (WAR), has now completed this assessment.

The manufacturer asked for safinamide to be placed on List 1A, in cluster O0N04BXAO V, with the COMT-inhibitor entacapone.

Safinamide is available as a film-coated tablet. Each film-coated table contains safinamide methanesulphonate, equivalent to 50 mg or 100 safinamide. It is a highly selective and reversible MAO-inhibitor. The degree to which the non-dopaminergic effects contribute to the general effects has not been established.

It is registered for the treatment of adult patients with idiopathic Parkinson's disease (PD), as add-on to a stable dose of levodopa alone or in combination with other PD medicinal products in mid-to-late stage fluctuating patients. The starting dose is 50 mg per day, which can be increased, based on individual clinical needs, to 100 mg per day.

Outcome of the assessment

Based on the criteria of mutual replaceability, safinamide film-coated tablets can be regarded as mutually replaceable with the other MAO-inhibitors, selegiline and rasagiline, which are already included in the GVS, in cluster 0N04BDAO V.

Zorginstituut Nederland's advice

Zorginstituut Nederland advises the Minister of Public Health, Welfare and Sport to include safinamide (Xadago®) in the GVS on list 1A, in cluster 0N04BDAO V, with a standard dose of 75 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.