



Acarizax® in cases of allergic rhinitis due to house dust mite

Summary of recommendations by *Zorginstituut Nederland* dated 26 June 2017

Zorginstituut Nederland carried out an assessment of the medicinal product Acarizax®, whereby they came to the following conclusion.

In a letter dated 10 April 2017 (CIBG-17-04265), the Minister of Health, Welfare and Sport asked *Zorginstituut Nederland* to carry out an assessment of whether Acarizax® is interchangeable with a drug currently included in the GVS. The Zorginstituut, advised by the Scientific Advisory Committee (WAR), has now completed this assessment.

Acarizax® (12 SQ-HDM SLIT = the dose unit for Acarizax; SQ is a method for standardisation on biological potency, major allergen content and complexity of the allergen extract; HDM is an abbreviation for house dust mite) is indicated for adults and adolescent patients (12-65 years) with persistent moderate to severe house dust mite allergic rhinitis, despite the use of symptomatic medication, diagnosed based on clinically relevant complaints, whereby the diagnosis was made based on a positive skin prick-test and/or a specific IgE-test for house dust mite.

It is available as an orodispersible tablet (sublingual tablet; lyophilisate). Each orodispersible tablet contains 12 SQ-HDM standardised allergen extract from *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*, house dust mites.

The recommended dose for adults (18-65 years) and adolescents (12-17 years) is daily one lyophilisate for oral use.

Assessment of interchangeability

Two drugs are currently included in the GVS for the indication 'persistent moderate to severe house dust mite allergic rhinitis, despite the use of symptomatic medication'. These are Alutard® and Depothal®, allergen extracts from house dust mites intended for subcutaneous immunotherapy. In 2008 CVZ determined that Alutard® and Depothal® could be regarded as interchangeable (CFH report 08/21).

Based on the current criteria, Acarizax® is not interchangeable with Alutard® and Depothal®, due to a different means of administration.

Based on the above, Acarizax® cannot be placed on List 1A. What must be examined is whether Acarizax® is eligible for placing on List 1B.

Therapeutic value

Zorginstituut Nederland has concluded that the therapeutic value of treatment with sublingual standardised allergen extract from house dust mites (Acarizax®) for adults and adolescents (12-65

years) with persistent moderate to severe house dust mite allergic rhinitis despite the use of symptomatic medication, is equal to that of treatment with subcutaneously administered allergen extracts of house dust mite (Alutard).

Budget impact analysis

The price of the sublingual product Acarizax® is the same as the price of the subcutaneous drugs that are currently used for these patients (incl. Alutard®). Even if Acarizax® were to take over the entire (current) market, this would not lead to additional costs. Additional costs would only result if patients who are currently not being treated with subcutaneous immunotherapy, start wanting to receive treatment with Acarizax® due to ease of use. These estimated total additional costs at the expense of the pharmacy budget are between €0.2 and 0.9 million in the 3rd year after inclusion in the GVS. Other economies may also be realised within the health care budgetary framework because the administration of Acarizax®, unlike that of Alutard®, can take place without medical supervision. These economies can amount to approximately €0.7 million per year.

On the grounds of the estimated budget impact, exemption has been granted from carrying out a pharmacoeconomic analysis.

Advice

Acarizax® is not interchangeable with any product in the GVS. A product that is not interchangeable and which has the same therapeutic value can only be placed on List 1B if no additional costs are involved. As the price of Acarizax® is the same as that of the subcutaneous drugs that are currently used for these patients (incl. Alutard®), and complete substitution does not lead to additional costs, the Zorginstituut advises the Minister to include the sublingual standardised allergen extract from house dust mites (Acarizax®; 12 SQ-HDM SLIT) on List 1B.

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.