



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport  
P.O. Box 20350  
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2025015010

Date 1 July 2025  
Re: GVS advice adjustment of further conditions for the standardised allergenic extract of house dust mites (Acarizax®) for moderate to severe rhinitis.

**National Health Care Institute**

Care  
Medicinal Products

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**Our reference**

2025015010

Dear Ms Jansen,

The National Health Care Institute advises you on the adjustment of the further conditions of standardised allergenic extract of house dust mites (12 SQ-HDM SLIT<sup>1</sup>) (Acarizax®) for the treatment of persistent moderate to severe rhinitis caused by house dust mites in the Medicine Reimbursement System (GVS). This advice was prompted by your request in the letter of 14 April 2025 (CIBG-25-08107).

Allergic rhinitis is an inflammation of the nasal mucosa. House dust mites are tiny animals that live in the dust in the house. An allergy to house dust mites can cause symptoms such as allergic rhinitis. Treatment with house dust mite extract can reduce allergic symptoms. There are already several extracts of such products available in the Netherlands. An expansion of the reimbursement is now requested for 12 SQ-HDM SLIT.

Registered indication

12 SQ-HDM SLIT (Acarizax®) is indicated for children and adult patients (5-65 years) with persistent moderate to severe allergic rhinitis caused by house dust mites despite the use of symptomatic medication, diagnosed based on clinically relevant signs, with the diagnosis supported by a positive skin prick test and/or specific IgE test for house dust mites.

In 2022, the National Health Care Institute concluded that 12 SQ-HDM SLIT has an equal value to the 100 IR/300LA HDM (Actair®), which is also administered sublingually. Both products are included in cluster OV01AABO V on List 1A of the GVS, with the following List 2 conditions:

Current condition 100 IR/300 IR HDM and 12 SQ-HDM:

Only for an insured person aged 12 years and older with persistent house dust mite-induced allergic rhinitis or rhinoconjunctivitis, diagnosed on the basis of

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<sup>1</sup> SQ-HDM is the dose unit for Acarizax®. SQ (standard quality) is a standardisation method for the biological strength, amount of major allergen and complexity of allergen extract. HDM is the abbreviation for house dust mites. SLIT tablet stands for sublingual immune therapy tablet.

clinical history and a positive house mite sensitisation test (skin prick test and/or specific IgE), despite adequate medical management.

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#### Claim by the marketing authorisation holder

For the registered indication, 12 SQ-HDM SLIT (Acarizax®) has an equivalent value compared to subcutaneously administered immunotherapy with allergen HDM extracts.

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The marketing authorisation is requesting an expansion of the further conditions.

#### **Advice**

The National Health Care Institute advises you to adjust the further condition only for 12 SQ-HDM as follows. The current condition for 100 IR/300 IR HDM remains unchanged. This is because in 2009, a paediatric study of 100 IR/300 IR HDM showed no significant treatment effect for 100 IR/300 IR HDM compared to placebo. Patients in both groups reported only a few symptoms during and after treatment and the study was discontinued early due to lack of effectiveness and as recommended by the Data and Safety Committee.<sup>2</sup>

#### **New condition 12 SQ-HDM:**

Only for an insured person with persistent house dust mite-induced allergic rhinitis or rhinoconjunctivitis, diagnosed on the basis of clinical history and a positive house dust mite sensitisation test (skin prick test and/or specific IgE), despite adequate medical management.

We explain the preparation of this advice below.

#### Substantive assessment

##### *Therapeutic value*

12 SQ-HDM SLIT is clustered with 100 IR/300 IR HDM. Because 100 IR/300 IR HDM is not registered for children under 12 years, we compare the results of 12 SQ-HDM SLIT with subcutaneous immunotherapy SQ-HDM SCIT (Alutard®), the current standard treatment in children up to and including 11 years of age with persistent moderate to severe rhinitis due to household dust mite.

Treatment with 12 SQ-HDM SLIT was investigated in the randomised, placebo-controlled MT-12 study in children aged 4-11 years (n=1460).<sup>3</sup> The efficacy of SQ-HDM SCIT was investigated in a randomised, double-blind, placebo-controlled study in patients aged 5 to 45 years (N=239). The mean age was approximately 19 years (N=239).<sup>4</sup> As subgroup analyses by specific age groups have not been performed, it is not possible to make an indirect comparison between 12 SQ-HDM SLIT and SQ-HDM SCIT in children aged 5-11 years.

In 2022, the National Health Care Institute concluded that SQ-HDM SLIT for adults and adolescents (12-65 years) with moderate to severe allergic rhinitis

<sup>2</sup> See: [SmPC Actair®](#) and [clinicaltrials.gov](#)

<sup>3</sup> Schuster *et al.*. Efficacy and safety of SQ house dust mite sublingual immunotherapy tablet (12 SQ-HDM) in children with allergic rhinitis/rhinoconjunctivitis with or without asthma (MT-12): a randomised, double-blind, placebo-controlled, phase III trial. *Lancet Reg Health Eur.* 2024 Nov 26;48:101136. doi: 10.1016/j.lanepe.2024.101136. eCollection 2025 Jan.

<sup>4</sup> Tabar *et al.* Double-blind comparative study of cluster and conventional immunotherapy schedules with *Dermatophagoides pteronyssinus*. *J Allergy Clin Immunol.* 2005 Jul;116(1):109-18. doi: 10.1016/j.jaci.2005.05.005.

caused by house dust mites despite the use of symptom-relieving remedies, is equivalent to SQ-HDM SCIT treatment. No difference in effectiveness between adults and adolescents was demonstrated.<sup>5</sup> The same randomised, double-blind, placebo-controlled study of 12 SQ-HDM SCIT in patients aged 5 to 45 years was used in the 2022 assessment.<sup>4</sup>

Based on the placebo-controlled data from the MT-12 study (12 SQ-HDM), the National Health Care Institute concludes that treatment with 12 SQ-HDM SLIT in children 5-12 years leads to similar results to treatment with 12 SQ-HDM SLIT in adolescents and adults.

Based on these different forms of indirect evidence, the National Health Care Institute concludes that 12 SQ-HDM SLIT in paediatric patients aged 5-11 years has an equal value compared to SQ-HDM SCIT for this indication.

*Budget impact analysis*

Adjustment of the further condition may lead to a possible shift in treatment to younger patients, as children who were previously ineligible for subcutaneous treatment may become eligible for sublingual treatment. Additionally, there will be a substitution of the subcutaneous treatments already administered to children aged 5-11 years. The cost of treatment with 12 SQ-HDM SLIT is slightly lower than the subcutaneous treatments. Shifting to younger patients does not lead to an increase in use. In short, adjusting the condition does not lead to any additional costs to the pharmaceutical budget.

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

M.J. Janssen  
*Chairperson of the Executive Board*

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<sup>5</sup> GVS advice Acarizax® for allergic rhinitis caused by house dust mites | Advice | National Health Care Institute