HAUTE AUTORITÉ DE SANTÉ

ALLERGY MEDICINE
New medicinal product
February 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

ACARIZAX (standardised allergen extract from the house dust mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*)

No clinical benefit demonstrated in the treatment of allergic rhinitis and asthma

Main points

- ACARIZAX, administered orally, has a Marketing Authorisation in adults with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication and/or house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis.
- Treatment is based on a diagnosis including a clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE).
- No clinical benefit has been demonstrated compared with usual treatment of these patients. This is a second-line treatment for:
  - persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication
  - non-severe forms of house dust mite allergic asthma in adults, with an FEV1 ≥ 70% of predicted value, not well controlled despite moderate to significant doses of inhaled corticosteroids, and associated with mild to severe house dust mite allergic rhinitis.

Therapeutic use

- Allergic rhinitis:

The first measure is to remove the allergen when possible. Medicinal treatment is based on H1-antihistamines and nasal corticosteroids. Only 2nd generation anti-H1s are recommended. Nasal corticosteroids are indicated in first-line in severe forms and in second-line in case of failure of anti-H1s. Oral corticosteroids should be avoided. If needed, they can be prescribed for short cycles. In perennial rhinitis, allergenic immunotherapy is indicated when the rhinitis is severe and/or prolonged, especially when there is a mild or moderate associated asthma. The main allergens are house dust mites.

- Allergic asthma associated with allergic rhinitis:

Therapeutic management of asthma is based on an escalation of therapeutic means with mainly two types of symptomatic medicinal products:
- rescue treatments: short-acting bronchodilators;
- long-term treatments: inhaled corticosteroids, long-acting beta-2 agonist or anticholinergic bronchodilators, montelukast, theophylline and, in severe refractory persistent asthma, oral corticosteroids and, possibly, omalizumab (anti-IgE) in severe allergic asthma, and mepolizumab (anti-IL-5) in eosinophilic asthma.

Sub-cutaneous allergenic immunotherapy can only be offered to patients with controlled asthma with FEV1 > 70% of predicted value due to the risk of bronchospasm. Currently, sublingual allergenic immunotherapy is used in the management of controlled and partially controlled asthma with an FEV1 ≥ 70% of predicted value. Allergenic immunotherapy may also be a treatment option when the allergy plays a predominant role in the asthma and especially when it is associated with rhinoconjunctivitis.

Role of the proprietary medicinal product in the therapeutic strategy

ACARIZAX is a second-line therapy in adults with:
- persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication

- non-severe forms of house dust mite allergic asthma, with an FEV1 ≥ 70% of predicted value, not well controlled despite moderate to significant doses of inhaled corticosteroids, and associated with mild to severe house dust mite allergic rhinitis.

Clinical data

- ACARIZAX has demonstrated a low efficacy compared to placebo in house dust mite allergic rhinitis in terms of symptoms and use of rescue medications (composite score of 0 to 24 points) after 12 months of treatment under real conditions of exposure to allergens: 5.71 with ACARIZAX versus 6.81 with the placebo, i.e. a difference of 1.09 points, (p = 0.004) at the clinical relevance threshold (≥ 1 point).
- In a study in an exposure chamber, in which rescue treatments were to be stopped 3 days before exposure, the amount of effect appeared to be greater in terms of symptom reduction compared to placebo.
- In non-severe house dust mite allergic asthma (FEV1 ≥ 70% of predicted value), not well controlled by a long-term treatment with inhaled corticosteroids, the reduction in the risk of the first moderate to severe exacerbation was 31% after 18 months of treatment.
- The most common adverse effects with treatment with standardised house dust mite allergen extract are local allergic-type reactions. Due to a risk of systemic allergic reactions (observed with sublingual grass pollen allergen extracts), the first oral lyophilisate should be taken under medical supervision.

Benefit of the medicinal product

- The actual clinical benefit* of ACARIZAX is low.
- ACARIZAX does not provide clinical added value** (CAV V) compared to usual management of patients.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 22 February 2017 (CT-15325) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.