NEW DRUGS

Dust mite allergen extract

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Approved indication: allergic rhinitis

Actair (Stallergenes)
sublingual tablets 100 IR and 300 IR

These tablets contain allergen extracts of European house dust mites and American house dust mites in a 1:1 mixture. Tablets come in two concentrations: 100 or 300 index of reactivity (IR). The IR is a defined unit relating to allergenicity of the extract in a skin-prick test.

The exact mechanism of how this product reduces the symptoms of allergic rhinitis caused by dust mites is unclear. It increases the IgG antibody to dust mites which is then thought to compete with specific IgE antibody that mediates the allergy. The extract is also thought to modify the T-cell response to dust mites.

In a trial of 509 adults with confirmed moderate to severe dust mite allergic rhinitis, two doses of the allergen extract (300 IR or 500 IR once daily) were compared to placebo. People with other clinically relevant sensitisations (e.g. hay fever, cat or dog allergy) and those with asthma were excluded. Participants received treatment for one year and were then followed for a further year. During the first year (at 8–12 months), mean scores of rhinitis symptoms were lower with the allergen extract than with placebo (see Table).[1] This difference between groups was maintained during the follow-up year. More patients in the 500 IR and 300 IR groups reported a marked improvement in their symptoms than in the placebo group. However, there was no difference in the use of oral and ophthalmic antihistamines and nasal corticosteroids between the groups after one or two years.

After a year of treatment, serum sampling confirmed that dust mite-specific IgG_4 had increased 2–3-fold with the active treatments. These concentrations were maintained for the one-year follow-up period. IgG_4 concentrations were unchanged with placebo and there were no relevant changes in IgE in any of the groups. The mean diameter of wheals after a skin-prick test with dust mite extract was reduced with the active treatments compared to placebo.

In a similarly designed but unpublished Japanese trial which enrolled adults and adolescents, symptom scores were also lower with a 300 IR sublingual dose compared to placebo. The proportion of patients reporting a marked improvement at the end of treatment was 22.2% with the active treatment and 9.7% with the placebo.

The most commonly reported adverse events with the allergen extract were in the mouth. Over half of people in the active treatment groups reported oral symptoms including oral pruritus and swelling of the mouth, tongue or lips. Throat irritation was also common (21–25%) and some patients reported pharyngeal oedema (4–7%).[1]

More people receiving the 500 IR tablet prematurely discontinued because of an adverse event than those receiving the 300 IR tablet or placebo (11.8% vs 10% vs 2.9%). This was mainly due to pharyngeal oedema, dyspepsia, nausea and mouth

Table **Efficacy of dust mite allergen extract compared to placebo for allergic rhinitis** [1]

Outcome	Daily treatment		
	300 IR tablet	500 IR tablet	Placebo
Average adjusted symptom score‡ (range 0–12):			
- after 1 year	3.18	3.09	3.87
- after 2 years	3.04	2.97	3.67
Proportion of people reporting marked improvement after 1 year	36.9%	33.1%	18%
Average rescue medication score§ (range 0–3):			
- after 1 year	0.33	0.23	0.32
- after 2 years	0.22	0.19	0.28

‡ based on the occurrence and severity of sneezing, rhinorrhoea, nasal pruritus, nasal congestion and ocular itching recorded by participants each day
§ based on the daily self-reported use of oral and ophthalmic antihistamines and nasal corticosteroids

oedema.[1] Eosinophilic oesophagitis has occurred with this type of sublingual immunotherapy. Treatment should be interrupted if persistent or severe dysphagia or chest pain occurs, and only restarted after consultation with a doctor.

This product is contraindicated in people with severe, uncontrolled asthma, an immune deficiency or autoimmune disorder, cancer or oral inflammation such as oral lichen planus, ulcerations or mycosis.

Although initiation of treatment is not recommended during pregnancy or lactation, there was no evidence of fetal harm in animal studies and it is not expected to have effects on breastfed babies.

Tablets should be taken on an empty stomach. They are placed under the tongue and then swallowed after they have completely disintegrated. Treatment should start with one 100 IR tablet on the first day, two 100 IR tablets on the second day and one 300 IR every day after that (maintenance dose). The first tablet should be given under medical supervision and the patient should be monitored for 30 minutes.

This product seems to reduce symptoms in patients with allergic rhinitis but did not decrease their use of symptomatic treatments. The most common treatment-related effects were reactions in the mouth and throat, including irritation and swelling. Some patients developed more serious allergic reactions so administration of the first dose should be supervised.

T T manufacturer provided additional useful information

REFERENCE

1. Bergmann KC, Demoly P, Worm M, Fokkens WJ, Carillo T, Tabar AI, et al. Efficacy and safety of sublingual tablets of house dust mite allergen extracts in adults with allergic rhinitis. J Allergy Clin Immunol 2014;133:1608-14.e6. http://dx.doi.org/10.1016/j.jaci.2013.11.012

The Transparency score (T) is explained in 'New drugs: transparency', Aust Prescr 2014;37:27.

A:

ANSWERS TO SELF-TEST QUESTIONS

1 True 2 True
3 False 4 True

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