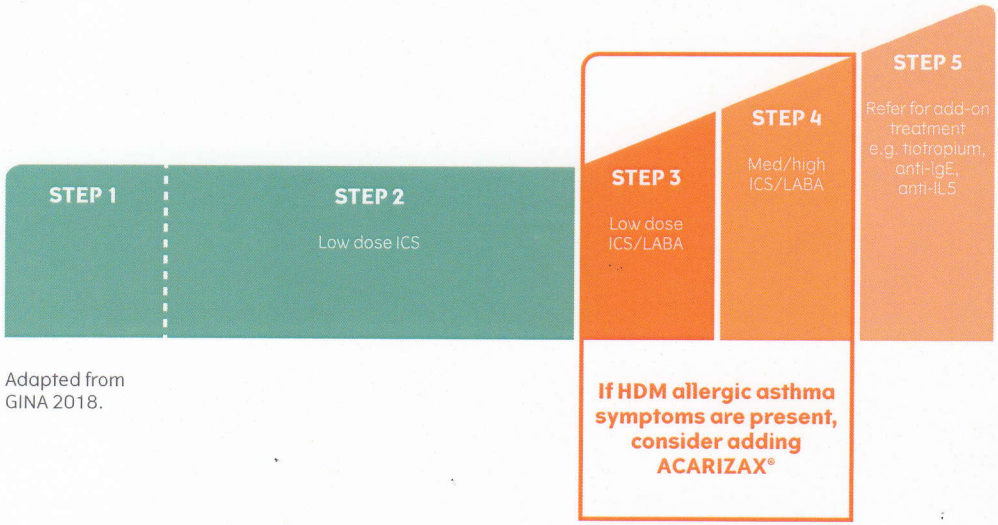

ALK
welcome home
A new way of treating
house dust mite
respiratory allergy
ACARIZAX®
Extract from
D. pteronyssinus
D. farinae

ACARIZAX® in Clinical Practice

GINA: highlighting the need to treat the allergic component

ACARIZAX® is recommended as add-on treatment for patients with house dust mite allergic asthma (steps 3 and 4) [3]



Adapted from GINA 2018.

Patients eligible for treatment with ACARIZAX®

Asthma not well controlled [3]

Indicated by one or more of the following:

- Nocturnal awakening due to asthma
- Increased daytime asthma symptoms
- Increased usage of asthma reliever medication
- Activity limitations due to asthma, e.g. missing work, school, sport, leisure

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Respiratory symptoms triggered by HDM [1]

- Sleep disturbance
- Nasal congestion and sneezing

Symptoms occur:

- all year round and can get worse in winter months when staying indoors
- during house dust mite exposure, e.g. when cleaning
- and fluctuate with change in environment, e.g. when travelling

Diagnosis

Perform confirmatory test for house dust mite sensitisation:

Skin prick test and/or Specific IgE [2]

ACARIZAX®

Initiate treatment provided patient meets the following:

FEV≥70% of predicted value at initiation of treatment[2]

No severe asthma exacerbation within the last three months[2]

No current acute respiratory tract infection[2]

Aged 18-65 years

Add on treatment with SABA/ICS

A three-year treatment course

One daily tablet for 3 years[1]

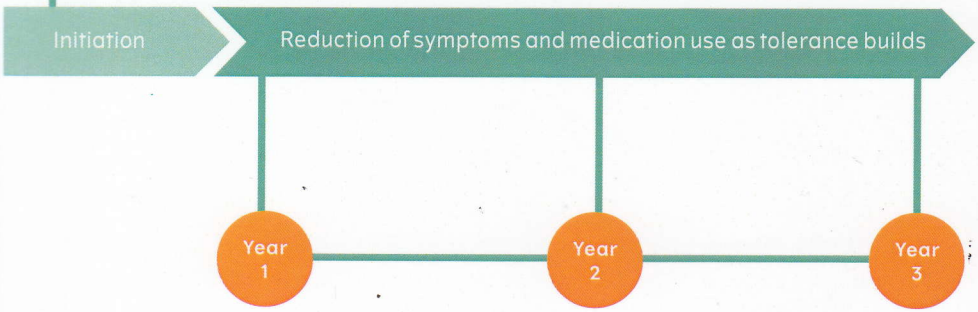
1st tablet

First tablet in clinic:

- Advice on how to take tablet
- Inform about side effects
- Medical supervision ≥ 30 minutes

Prescribe ACARIZAX® 1 tab daily

- FEV>70% of predicted value at initation of treatment[2]
- No severe asthma exacerbation within the last three months
- No current acute respiratory tract infection
- Should be initiated by physicians with experience in treatment of allergic disease



Follow-up visits recommended at least once yearly:**

- Monitor outcome of treatment
- Evaluate symptoms, asthma control and medication use
- Check adherence
- If no treatment effect after 1 year it is recommended to discontinue treatment

How to take ACARIZAX®

Once-daily tablet for 3 years [1]

- Placed under the tongue, with dry fingers
- No water required
- No special storage conditions required

Dissolves rapidly [1]

- Avoid swallowing for about 1 minute
- Food and drink should not be taken for the following 5 minutes

First tablet [2]

- Should be taken under medical supervision
- ≥ 30 minutes

Managing patient expectations

Improvement in symptoms expected after 8–14 weeks [2]

Local side effects are common at start of treatment and they: [2]

- can include itchy mouth and throat, swollen lips and tongue
- are a natural reaction by the immune system towards the allergen in the tablet
- subside with ongoing treatment

Abbreviated Summary of Product Characteristics

Product information for ACARIZAX®

ACARIZAX is available as a licensed pharmaceutical product having been granted marketing authorisation by regulatory authorities. Refer to the complete Summary of Product Characteristics before prescribing. **Pharmaceutical form and composition:** ACARIZAX oral lyophilisates (tablets) for allergy immunotherapy contains standardised allergen extract from the house dust mites Dermatophagoides pteronyssinus and Dermatophagoides farinae at the strength of 12 SQ-HDM per tablet. **Therapeutic indications:** ACARIZAX is indicated in adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation with at least one of the following conditions: persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication, house dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. **Posology and method of administration:** It is recommended that the first tablet is taken under medical supervision (at least 30 minutes). The daily dose is one tablet to be placed under the tongue. Avoid swallowing for about 1 minute. Food and beverage should not be taken for the following 5 minutes. Treatment should be initiated by physicians with experience in treatment of allergic diseases. **Contraindications:** Hypersensitivity to excipients; patients with FEV1 <70% of predicted value (after adequate pharmacological treatment) at initiation of treatment; patients who have experienced a severe asthma exacerbation within the last 3 months; in patients with asthma and experiencing an acute respiratory tract infection, initiation of ACARIZAX treatment should be postponed until the infection has resolved; patients with active or poorly controlled autoimmune diseases, immune defects, immunodeficiencies, immunosuppression or malignant neoplastic diseases with current disease relevance; patients with acute severe oral inflammation or oral wounds. **Special warnings and precautions for use:** Asthma is a risk factor for severe systemic allergic reactions. ACARIZAX is not intended to treat acute asthma exacerbation and should initially be used as add on therapy. Abrupt discontinuation of asthma controller medication is not recommended. Initiation of ACARIZAX in patients who have previously had a systemic allergic reaction to subcutaneous house dust mite immunotherapy should be carefully considered. Oral inflammation, eosinophilic esophagitis, autoimmune diseases in remission, cardiac diseases. Concomitant treatment with tricyclic antidepressants, MAOIs inhibitors, COMT inhibitors, and/or beta-blockers. **Interaction with other medicinal products and other forms of interaction:** Concomitant therapy with symptomatic anti-allergic medications may increase the tolerance level of the patient to immunotherapy. **Pregnancy and lactation:** No clinical experience. Animal studies do not indicate increased risk to the foetus. Treatment with ACARIZAX should not be initiated during pregnancy. **Undesirable effects:** Subjects taking ACARIZAX should primarily expect mild to moderate local allergic reactions to occur

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within the first few days and subsiding again with continued treatment (1-3 months). For the majority of events, the reaction should be expected to start within 5 minutes after intake and abate after minutes to hours. The following adverse reactions are reported as being very common (≥1/10), or common (≥1/100 to <1/10), based on data from clinical trials: nasopharyngitis, bronchitis, pharyngitis, rhinitis, sinusitis, dysgeusia, eye pruritus, ear pruritus, throat irritation, asthma, dysphonia, dyspnoea, oropharyngeal pain, pharyngeal oedema, lip oedema, oedema mouth, oral pruritus, abdominal pain, diarrhoea, dysphagia, dyspepsia, gastrooesophageal reflux disease, glossodynia, glossitis, , lip pruritus, mouth ulcerations, oral pain, tongue pruritus, nausea, oral discomfort, oral mucosal erythema, oral paraesthesia, stomatitis, tongue oedema, vomiting, pruritus, urticarial, chest discomfort, fatigue. In case of acute worsening of asthma symptoms, severe systemic allergic reactions, angioedema, difficulty in swallowing, difficulty in breathing, changes in voice, hypotension or feeling of fullness in the throat, a physician should be contacted immediately. **Paediatric population:** ACARIZAX is not intended for treatment of children <18 years of age. **Overdose:** In phase I studies adult patients with house dust mite allergy were exposed to doses up to 32 SQ-HDM. If doses higher than the recommended daily dose are taken, the risk of side effects may increase, including the risk of systemic allergic reactions or severe local allergic reactions. **Excipients:** Gelatine (fish source), mannitol, sodium hydroxide. **Shelf life:** 4 years. Content of container: Aluminium blister cards with 30 tablets. **Marketing authorisation holder:** ALK-Abelló A/S, Bøge Alle 6-8, DK-2970 Hørsholm, Denmark. **Marketing authorisation number(s):** PA1255/010/001. **Updated:** January 2019 1416HDMIR

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie

Adverse events should also be reported to ALK-Abelló Ltd

References

1. Bousquet J et al. Allergy. 2008;63(Suppl 86):8-160 **2.** ACARIZAX® 12 SQ-HDM oral lyophilisate Summary of Product Characteristics. ALK Abello A/S, August 2015 **3.** Global Initiative for Asthma (GINA) 2018 GINA Report, Global Strategy for Asthma Management and Prevention