# Licensed treatment for house dust mite respiratory allergy[1,2]

**Evidence-based**

Building on a legacy of both **evidence** and **experience***[1,3-5]

**Proven efficacy**

A welcome answer for **both allergic rhinitis** and **allergic asthma** in adults with HDM respiratory allergy[1,4,5]

**At-home treatment†**

A **licensed, proven** and **patient-centric** approach to HDM respiratory allergy[1,6,7]

**Guidelines**

HDM SLIT recommended on ICGP / GINA guidelines[8,9]

†The first dose should be taken under medical supervision, and the patient should be monitored for at least 30 minutes. Please refer to the ACARIZAX® D. Pteronyssinus & D. farinae Summary of Product Characteristics for more detailed information.[1]

Prescribing information and adverse event reporting is available on the final page

IE-AZX-2200003 January 2023

For healthcare professionals only

HDM, house dust mite; ICGP, Irish College of General Practitioners; GINA, Global Initiative for Asthma; SLIT, Sublingual Immunotherapy

*Trials: MT-01: 2005-002151-41; MT-02: 2006-001795-20 / NCT00389363; MT- 03: 2007-000402-67; MT-04: 2010-018621-19 / NCT01433523; MT-06: 2011- 002277-38 / NCT01454544; TO-203-1: JapicCTI-111624(en); TO-203-3-1: JapicCTI- 121847(en); TO-203-3-2: JapicCTI-121848(en); TO-203-3-3: JapicCTI-152953(en); MK-8237-001: NCT01700192; MK-8237-003: 2012-001855-38 / NCT01644617; MK-8237-009: 2012-005621-70 / NCT01852825; MITI3001: ID:1000603874; MT-09: regID 2006L10180.

ACARIZAX®

D. Pteronyssinus & D. farinae

# House dust mite allergic patients who may benefit from ACARIZAX®[1]

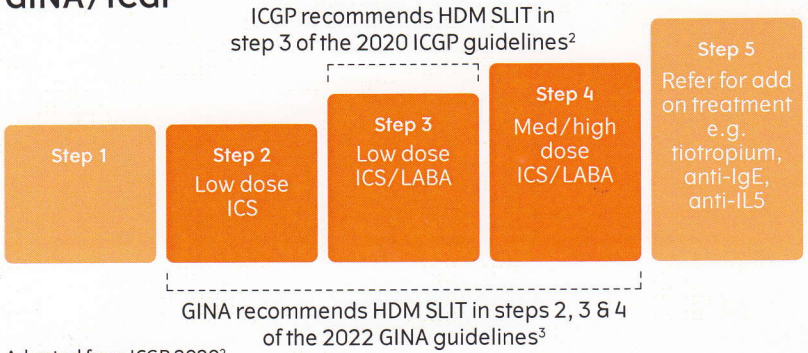
## When to consider

- ACARIZAX® is indicated in adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with at least one of the following conditions:[1]
  - Persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication[1]
  - House dust mite allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe house dust mite allergic rhinitis. Patients' asthma status should be carefully evaluated before the initiation of treatment*[1]

ACARIZAX® is indicated in adolescents (12-17 years) diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe house dust mite allergic rhinitis despite use of symptom-relieving medication.

*Provided patient has: $FEV_1$ ≥70% of predicted at initiation of treatment, no severe asthma exacerbation in last 3 months, and no current acute respiratory tract infection.

## GINA/ICGP




Adapted from ICGP 2020[2]

### ICGP/GINA guidelines[2,3]

ICGP and GINA recommend HDM SLIT as an option in adult patients with sub-optimally controlled asthma despite low to high-dose ICS, with allergic rhinitis who are sensitised to house dust mite and have $FEV_1$>70%

SLIT, sublingual immunotherapy; IgE, immunoglobulin, class E; GINA, Global Initiative for Asthma; FEV1, forced expiratory volume in the first second; ICS, inhaled corticosteroid; anti-IgE, anti-immunoglobulin class E; anti-IL-5, anti-interleukin-5; HDM, house dust mite; LABA, long-acting beta-agonists; ICGP, Irish College of General Practitioners

# House dust mite allergic rhinitis and asthma often co exists[1]

**Allergic rhinitis and allergic asthma**

**Approximately 50%** of all patients with **HDM respiratory allergy** suffer from both **allergic rhinitis** and **allergic asthma**[1]

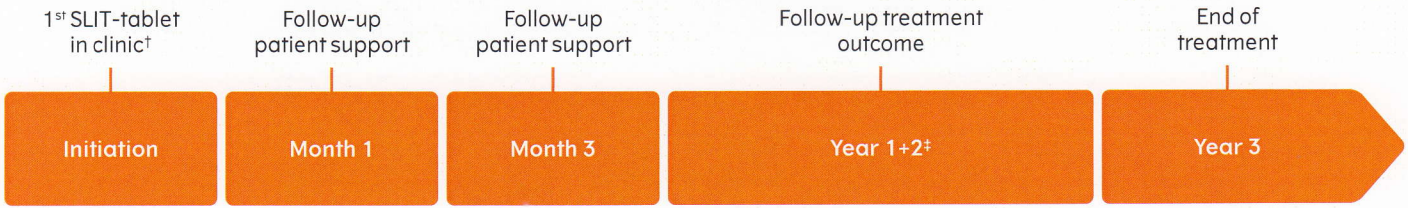
**Allergic asthma**


**>50%** of all **allergic asthma patients** have **HDM allergy**[2]

Adults suffering from HDM respiratory allergy will benefit from an AIT treatment that addresses both HDM allergic rhinitis and allergic asthma[3]

# 3-year AIT therapy management plan*[4]

## First year of therapy is pivotal to complete the 3-year treatment[5,6]




*Suggested management plan. Long-term efficacy for ACARIZAX® has not yet been established. Please refer to the ACARIZAX® Summary of Product Characteristics for more detailed information.[7]

†The first dose should be taken under medical supervision and the patient should be monitored for at least 30 minutes to enable discussion and possible treatment of any immediate side effects. Please refer to the ACARIZAX® Summary of Product Characteristics for more detailed information.[7]

‡ If no improvement is observed during the first year of treatment with ACARIZAX® there is no indication for continuing treatment. Please refer to the ACARIZAX® SmPC.[7]

HDM, house dust mite; AIT, allergy immunotherapy; SLIT, sublingual immunotherapy; SmPC; Summary of Product Characteristics

# ACARIZAX® – A welcome relief from house dust mite allergic rhinitis[1,2]

## Clinically relevant efficacy with significant reductions vs placebo in all rhinitis symptoms and medication use[1]

**- 16%**

Median reduction of nose symptoms[1,2] vs placebo

(Absolute reduction = 0.54)
p=0.003

**- 13%**

Median reduction of eye and nose[1,2] symptoms vs placebo

(Absolute reduction = 1.21)
p=0.029

**- 21%**

Median reduction in medication use[1,2] vs placebo

(Absolute reduction = 0.60)
p=0.024

## Early onset of effect

Significant and sustained reduction in the total combined rhinitis score after 14 weeks and a sustained year-round treatment effect demonstrated[2]

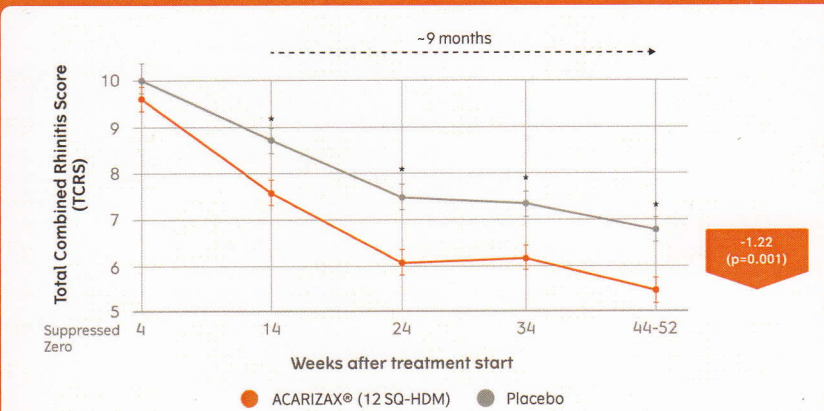


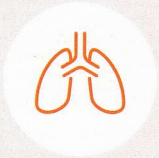

Figure adapted from Demoly et al
Error bars: Standard error of difference in adjusted means
*Statistically significant difference to placebo

All patients had access to symptom-relieving medications[1,2]

TCRS, total combined rhinitis score; SQ-HDM, the dose unit for ACARIZAX®; SQ is a method for standardisation on biological potency, major allergen content and complexity of the allergen extract

# ACARIZAX® - Welcome underlying protection for your allergic asthma adult patients[1,2]

Treats the underlying cause of house dust mite allergic asthma* to provide your patients with the extra protection they need[1,2]



**- 34%**

**Reduction vs placebo in risk of moderate or severe asthma exacerbations** during ICS reduction

59 vs 83 HR=0.66 (p=0.017)[1]

## ACARIZAX® significantly improved disease control in analysis of secondary endpoints vs placebo:[1]

**- 36%**

reduction in risk of **nocturnal awakening** or **increase of daily symptoms**

39 vs 57 HR =0.64 (p=0.031)

**- 42%**

reduction in risk of **deterioration in lung function**

30 vs 45 HR =0.58 (p=0.022)

**- 48%**

reduction in risk of increased **SABA use**

18 vs 32 HR =0.52 (p=0.029)

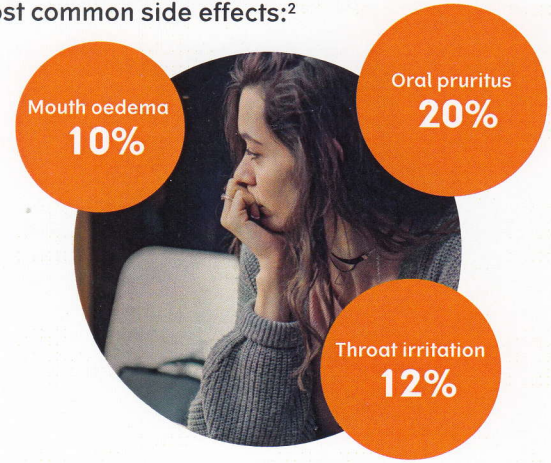
ACARIZAX® (n=248)
Placebo (n=257)

ICS, inhaled corticosteroids; SABA, short acting beta agonists; HR; hazard ratio

*The primary endpoint of this study was the time to first moderate or severe asthma exacerbation from the start of the ICS reduction/withdrawal period.

# ACARIZAX® is a well-tolerated treatment option for house dust mite allergic rhinitis and allergic asthma[1-4]

**Most common side effects:[2]**




First dose under medical supervision for at least 30 minutes[1]

**Likelihood of adverse events should be discussed with the patient:[1,2]**

- Typically, adverse reactions start within 5 minutes after intake and abate after minutes to hours[1]
- Side effects typically occur at the start of treatment and subside within days or weeks[2]

**Treatment related adverse events are common (in approximately half of patients); however, >97% are mild-to-moderate:[2]**

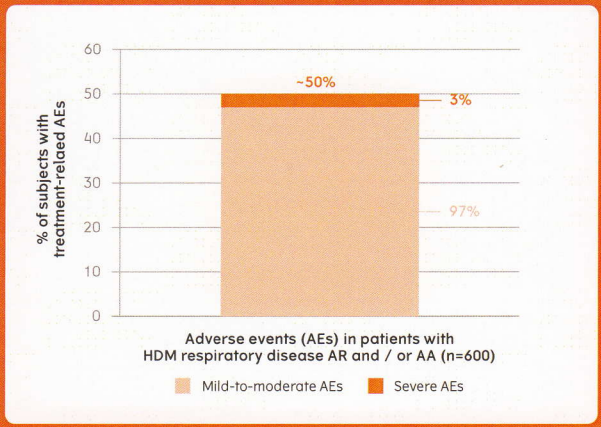



Figure adapted from Emminger W et al.[2]

AEs, adverse events; HDM, house dust mite; AA, allergic asthma; AR, allergic rhinitis

# References:

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2. Virchow JC et al. JAMA 2016;315:1715-25


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2. Emminger W et al. Int Arch Allergy Immunol 2017;174:35-44
3. Virchow JC et al. JAMA 2016;315:1715-25
4. Demoly P et al. J Allergy Clin Immunol 2016;137:444-51

# ACARIZAX® abbreviated Summary of Product Characteristics

**PRESCRIBING INFORMATION**
Refer to the Summary of Product Characteristics (SmPC) before prescribing

**ACARIZAX®** 12 SQ-HDM oral lyophilisate (tablet) for allergy immunotherapy contains standardised allergen extract from the house dust mites *Dermatophagoides pteronyssinus and Dermatophagoides farinae*. **Indications:** 1) Indicated in adult patients (18-65 years) diagnosed by clinical history and a positive test of house dust mite (HDM) sensitisation (skin prick test and/or specific IgE) with at least one of these conditions: persistent moderate to severe HDM allergic rhinitis despite use of symptom-relieving medication, or HDM allergic asthma not well controlled by inhaled corticosteroids and associated with mild to severe HDM allergic rhinitis. Patients' asthma status should be carefully evaluated before the initiation of treatment. 2) Indicated in adolescents (12-17 years) diagnosed by clinical history and a positive test of HDM sensitisation (skin prick test and/or specific IgE) with persistent moderate to severe HDM allergic rhinitis despite use of symptom-relieving medication. **Posology and administration:** Treatment should be initiated by physicians with experience in treatment of allergic diseases. The recommended dose for adults and adolescents (12-17 years) is one oral lyophilisate (12 SQ-HDM) daily. The first tablet should be taken under medical supervision for at least half an hour. 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. (Allergic rhinitis: Use in children <12 years of age has not been established. Allergic asthma: Use in children <18 years of age has not been established.) Not intended for use in adults >65 years of age. **Contraindications:**Hypersensitivity to excipients. Predicted $FEV_1$ <70% (after adequate pharmacological treatment) at initiation of treatment. Severe asthma exacerbation within the last 3 months. Patients with asthma and experiencing an acute respiratory tract infection, initiation of treatment should be postponed. Active or poorly controlled autoimmune diseases, immune defects, immunodeficiencies, immunosuppression or malignant neoplastic diseases with current disease relevance. Acute severe oral inflammation or oral wounds.
**Special warnings and precautions:** 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. Treatment should be discontinued and a physician should be contacted immediately in case of severe systemic allergic reactions, severe asthma exacerbation, angioedema, difficulty in swallowing, difficulty in breathing, changes in voice, hypotension or feeling of fullness in the throat. One option for treating severe systemic allergic reactions is adrenaline. The effects of adrenaline may be potentiated in patients treated with tricyclic antidepressants, MAOIs and/or COMT inhibitors with possible fatal consequences. The effects of adrenaline may be reduced in patients treated with beta-blockers. Initiation in patients who have previously had a systemic allergic reaction to subcutaneous HDM immunotherapy should be carefully considered. Oral inflammation or oral wounds, eosinophilic esophagitis, autoimmune diseases in remission, cardiac disease. ACARIZAX may contain trace amounts of fish protein. **Interactions:** Concomitant therapy with symptomatic anti-allergic medications may increase the tolerance level of the patient to immunotherapy.
**Pregnancy and lactation:** Treatment should not be initiated during pregnancy. No clinical data are available for use during lactation. **Undesirable effects:** Expect mild to moderate local allergic reactions to occur within the first few days and subsiding with continued treatment (1-3 months). For most events, the reaction should be expected to start within 5 minutes after intake and abate after minutes to hours. More severe oropharyngeal allergic reactions may occur. Severe acute worsening of asthma symptoms and serious systemic allergic reactions, including anaphylaxis, have been reported. Hypertensive crisis has been reported following respiratory distress shortly after intake. **Very common adverse reactions:** nasopharyngitis, ear pruritus, throat irritation, lip oedema, mouth oedema, oral pruritus. **Common:** bronchitis, pharyngitis, rhinitis, sinusitis, dysgeusia, eye pruritus, asthma, cough, dysphonia, dyspnoea, oropharyngeal pain, pharyngeal oedema, abdominal pain, diarrhoea, dysphagia, dyspepsia, gastrooesophageal reflux disease, glossodynia, glossitis, lip pruritus, mouth ulceration, oral pain, tongue pruritus, nausea, oral discomfort, oral mucosal erythema, oral paraesthesia, stomatitis, tongue oedema, vomiting, pruritus, urticaria, chest discomfort, fatigue. Rare but serious side effects include, laryngeal oedema, tracheal oedema and angioedema. **Consult the SmPC for details of adverse reactions.**
**Overdose:** 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.
**Legal Category:** Prescription-Only Medicine (POM). **Marketing Authorisation Holder**: ALK-Abelló A/S, Bøge Alle 6-8, DK-2970 Hørsholm, Denmark. **Marketing Authorisation Number:** PA1255/010/001. **Updated:** June 2022. 2022-288HDMIR

**Adverse events should be reported using the HPRA Pharmacovigilance Website: www.hpra.ie**
**Adverse events should also be reported to ALK at drugsafetyie@alk.net**