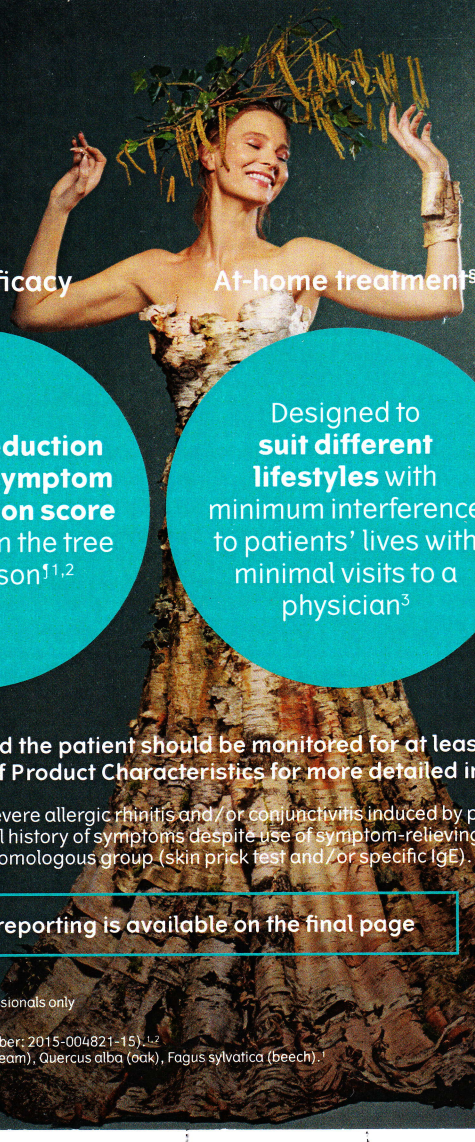
# This season's must have



**Evidence-based**

The only tree pollen SLIT-tablet with **confirmed cross-reactivity** within the birch homologous group*†[1,2]

**Proven efficacy**

Significant **reduction** in combined **symptom and medication score vs placebo**‡ in the tree pollen season¶[1,2]

**At-home treatment**[§]

Designed to **suit different lifestyles** with minimum interference to patients' lives with minimal visits to a physician[3]

**§ The first dose should be taken under medical supervision, and the patient should be monitored for at least 30 minutes. Please refer to the ITULAZAX® ▼ Betula verrucosa Summary of Product Characteristics for more detailed information.[1]**

ITULAZAX® is indicated in adult patients for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group.[1] ITULAZAX® is indicated in patients with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE).

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

IE-IZX-2200003 January 2023

For healthcare professionals only

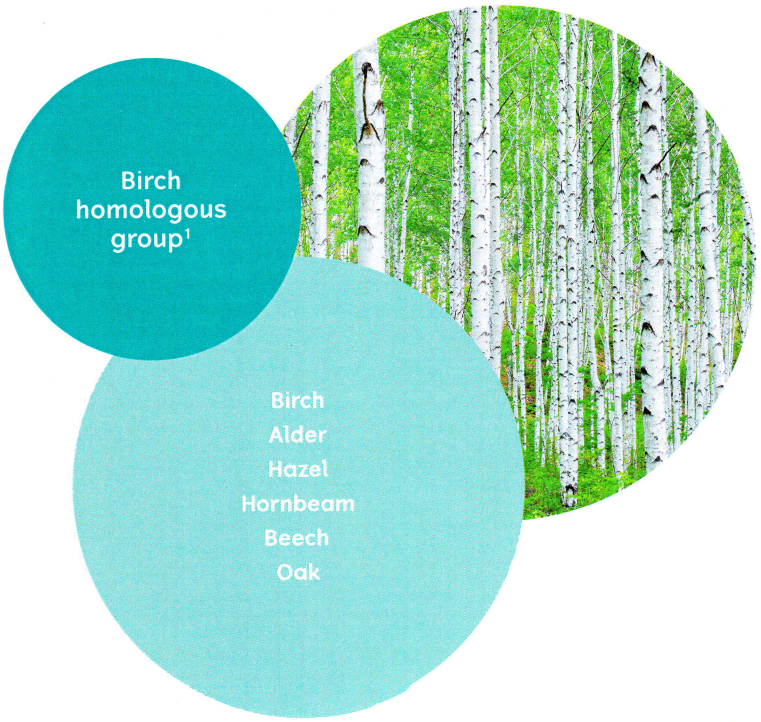
ITULAZAX® ▼
Betula verrucosa

SLIT, sublingual immunotherapy; IgE, immunoglobulin class E
*Demonstrated for birch, alder, and hazel in a randomised double-blind placebo-controlled phase III clinical trial (EudraCT Number: 2015-004821-15).[1,2]
† Birch homologous group: Betula verrucosa (birch), Alnus glutinosa (alder), Corylus avellana (hazel), Carpinus betulus (hornbeam), Quercus alba (oak), Fagus sylvatica (beech).[1]
‡ All patients had access to symptom-relieving medications.[2]
¶ Tree pollen season: Defined as days included in combined alder, hazel, and birch pollen seasons.

# Immunological cross-reactivity of allergens within the birch homologous group*[1-4]

## Supported by EMA guidelines[5,6]

- One member of a homologous group is selected as the representative allergen to evaluate efficacy and safety of allergen immunotherapy
- The number of allergen extracts in a mixture should be kept to a minimum regardless of homology and cross-reactivity of the individual allergens




### Cross-reactivity[7,8]

Betula verrucosa (white birch) is a representative allergen for the **birch homologous group***[5] and is the standardised allergen extract in ITULAZAX®.[7] Due to the **cross-reactivity** within the **birch homologous group**[1-4], ITULAZAX® can provide therapeutic effect to cover allergy to other members of the birch homologous group.

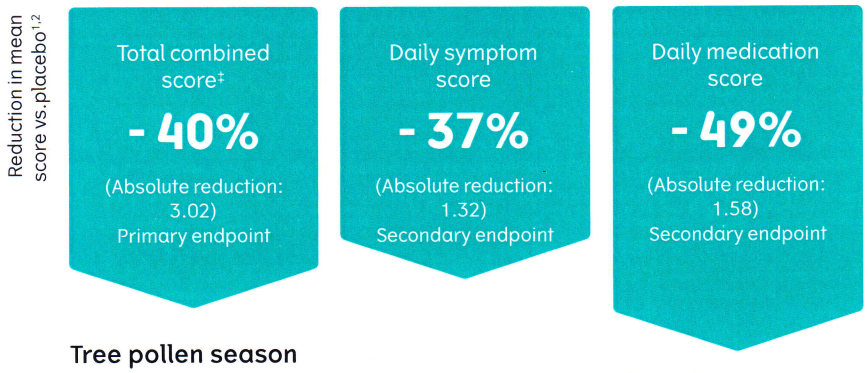
EMA, European Medicines Agency

*Birch homologous group: Betula verrucosa (birch), Alnus glutinosa (alder), Corylus avellana (hazel), Carpinus betulus (hornbeam), Quercus alba (oak), Fagus sylvatica (beech).[7]

# ITULAZAX® – Significantly reduces allergy symptoms and the need for symptom-relieving medication[1,2]

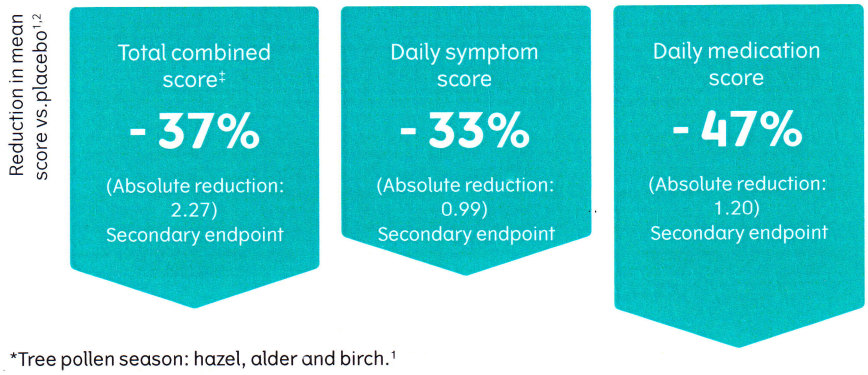
## Significant efficacy demonstrated for all primary and secondary end points across the tree pollen season*†‡[1,2]

### Birch pollen season




Placebo (n=292), ITULAZAX® (n=283)
P<0.0001 for all scores vs. Placebo.
All patients had access to symptom-relieving medications.[2]
Adapted from Biedermann T et al.[2]

### Tree pollen season




Placebo (n=292), ITULAZAX® (n=283)
P<0.0001 for all scores vs. Placebo.
All patients had access to symptom-relieving medications.[2]
Adapted from Biedermann T et al.[2]

*Tree pollen season: hazel, alder and birch.[1]
†Demonstrated in a randomised double-blind placebo-controlled phase III clinical trial (EudraCT Number: 2015 – 004821 - 15).[1,2]
‡Total combined score = daily symptom score + daily medication score.

# ITULAZAX® – Improves quality of life[1]

## ITULAZAX® significantly improves quality of life during the birch and tree pollen seasons*[1,2]

### Birch pollen season

Relative RQLQ difference vs. placebo

**-31%**

(Absolute reduction: 0.45)

Placebo (n=292; RQLQ adjusted mean 1.45), ITULAZAX® (n=283; RQLQ adjusted mean 0.99).
P<0.0001
All patients had access to symptom-relieving medications.[2]
Adapted from Biedermann T et al.[2]

### Tree pollen season

Relative RQLQ difference vs. placebo

**-28%**

(Absolute reduction: 0.37)

Placebo (n=292; RQLQ adjusted mean 1.32), ITULAZAX® (n=283; RQLQ adjusted mean 0.95).
P<0.0001
All patients had access to symptom-relieving medications.[2]
Adapted from Biedermann T et al.[2]

RQLQ, Rhinoconjunctivitis Quality of Life Questionnaire
*Tree pollen season: hazel, alder and birch.[1]

# Offer your patients at-home treatment with ITULAZAX®*

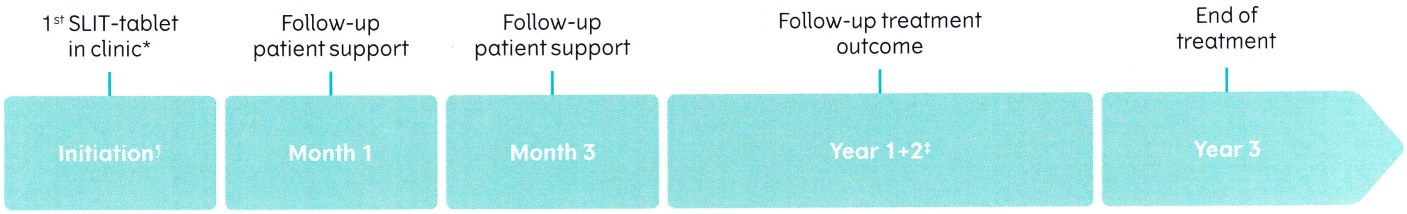
## Patients prefer AIT treatment with fewer and shorter physician visits[1]

- Once-daily administration*[2]
- First dose given under medical supervision*[2]
- No dose titration*[2]
- One minute sublingual holding time[2]
- No special storage conditions[2]

Effective treatment you can take at home*[1,2]

## 3-year AIT therapy management plan†[3]

### First year of therapy is pivotal to complete the 3-year treatment[4,5]




*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 any immediate side effects. Please refer to the ITULAZAX® Summary of Product Characteristics for more detailed information.[2]

† Suggested management plan. Long-term efficacy for ITULAZAX® has not yet been established. Please refer to the ITULAZAX® Summary of Product Characteristics more detailed information.[2]

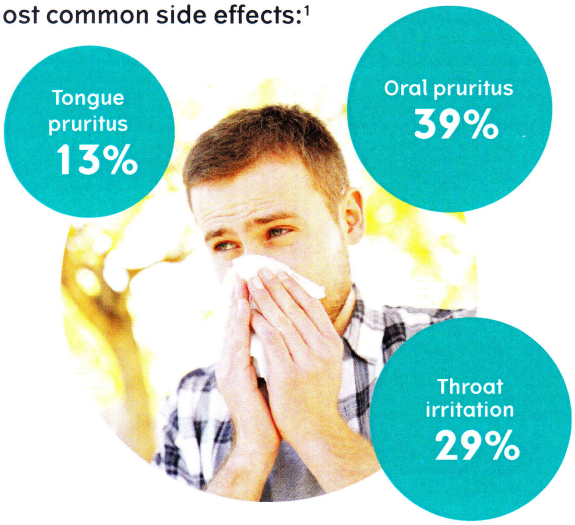
‡ If no improvement is observed during the first year of treatment with ITULAZAX® there is no indication for continuing treatment. Please refer to the ITULAZAX® SmPC

¶ It is recommended that treatment with ITULAZAX® should be initiated outside the pollen season and continued during the tree pollen season. Clinical effect during the tree (birch homologous group) pollen season has been demonstrated when treatment is initiated at least 16 weeks prior to the expected start of the tree (birch homologous group) pollen season and continued throughout the season.[2]

AIT, allergy immunotherapy; SLIT, sublingual immunotherapy; SmPC, Summary of Product Characteristics

# Local side effects are often mild to moderate, transient and an expected immune system reaction to the allergen[1,2]

**Most common side effects:**[1]




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

**AEs are often mild to moderate and transient**[1,2]

| AEs | Median onset of AE, for AEs starting on the first day of treatment | Median duration of AE from onset until resolution* |
|---|---|---|
| Oral pruritus | 2 minutes | 8 days |
| Throat irritation | 5 minutes | 7.5 days |
| Tongue pruritus | 2 minutes | 5 days |

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

- Typically, adverse reactions start within 10 minutes after intake and abate within an hour[1]
- Side effects typically occur at the start of treatment and subside within a few months (in many cases within a week or two)[1]

AE, adverse event

*Typically, local reactions had onset within few minutes after treatment and recurrent events had median daily durations of 10–45 min.[2]

# References:

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References:


1. ITULAZAX® Summary of Product Characteristics
2. Biedermann T et al. J Allergy Clin Immunol 2019;143(3):1058-66.e6
3. Damm K et al. Health Econ Rev 2016;6(32):1-9


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1. Niederberger V et al. J Allergy Clin Immunol 1998;102:579-591
2. Petersen BN et al. Allergy 1988;43:353-62
3. Wihl JA at al. Allergy 1988;43:363-9
4. Ipsen H et al. Allergy 1988;43:370-7
5. EMA guideline on allergen products: Production and quality issues (EMEA/CHMP/BWP/304831/2007)
6. EMA guideline on the clinical development of products for specific immunotherapy for the treatment of allergic diseases (EMEA/EWP/18504/2006)
7. ITULAZAX® Summary of Product Characteristics
8. Kleine-Tebbe J et al. Allergy 2020;75(6):1327-36


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1. ITULAZAX® Summary of Product Characteristics
2. Biedermann T et al. J Allergy Clin Immunol 2019;143(3):1058-66.e6


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1. ITULAZAX® Summary of Product Characteristics
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1. Damm K et al. Health Econ Rev 2016;6:1-9
2. ITULAZAX® Summary of Product Characteristics
3. Roberts G et al. Allergy 2018;73:765-98
4. Novak N et al. EMJ 2018;3:21-9
5. Allam JP et al. J Allergy Clin Immunol 2018;141:1898-901


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References:


1. ITULAZAX® Summary of Product Characteristics
2. Biedermann T et al. J Allergy Clin Immunol. 2019;143:1058-66.e6

# ITULAZAX® ▼abbreviated Summary of Product Characteristics

**PRESCRIBING INFORMATION**

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

ITULAZAX® 12 SQ-Bet oral lyophilisate (tablet) for sublingual allergy immunotherapy, contains standardised allergen extract of pollen from white birch (Betula verrucosa).

**Indications:** The treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group in adults with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE). The birch homologous group include: Betula verrucosa (birch), Alnus glutinosa (alder), Carpinus betulus (hornbeam), Corylus avellana (hazel), Quercus alba (oak), Fagus sylvatica (beech).

**Posology and Administration:** The recommended daily dose for adults is one oral tablet (12 SQ-Bet) to be placed under the tongue. The first tablet should be taken under medical supervision for at least half an hour. Avoid swallowing for about 1 minute. Food and beverage should not be taken for the following 5 minutes. Clinical effect during the tree (birch homologous group) pollen season has been demonstrated when treatment is initiated at least 16 weeks prior to the expected start of the tree pollen season and continued throughout the season. Treatment should be initiated by physicians with experience in treatment of allergic diseases. Not for use in patients <18 years of age.

**Contraindications:** Hypersensitivity to excipients, malignancy or active systemic disorders affecting the immune system, severe oral inflammation or oral wounds. Predicted $FEV_1$<70% (after adequate pharmacologic treatment) at initiation of treatment. Severe asthma exacerbation or uncontrolled asthma within last 3 months prior to initiation.

**Special Warnings and Precautions:** Treatment should be discontinued, and a physician should be contacted immediately in case of severe systemic allergic reactions, severe asthma exacerbation, severe pharyngeal oedema, 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, mono amino oxidase inhibitors (MAOIs) and/or COMT inhibitors with possible fatal consequences. The effects of adrenaline may be reduced in patients treated with beta-blockers. Patients with cardiac disease may be at increased risk in case of severe systemic allergic reactions. Initiation in patients who have previously had a systemic allergic reaction to subcutaneous tree pollen allergy immunotherapy should be carefully considered. Asthma is a known risk factor for systemic reactions. In severe oral inflammation, oral wounds or following oral surgery or tooth loss, initiation of treatment should be postponed. In severe or persisting gastro-oesophageal symptoms, medical evaluation must be sought. ITULAZAX 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 the use during lactation.

**Undesirable Effects:** Expect mild to moderate local allergic reactions to occur within the first few days of treatment and disappear within a few months (in many cases within a week or two). For most events, the reaction starts within 10 minutes after intake of ITULAZAX on each day of occurrence and abate within an hour. More severe local allergic reactions may occur. Systemic allergic reactions, including anaphylactic reactions, are known risks. Oral allergy syndrome can occur upon ingestion of certain raw vegetables, fruits or nuts. **Very common adverse reactions:** ear pruritus, throat irritation, oedema mouth, oral pruritus, paraesthesia oral, tongue pruritus. Common: rhinitis, oral allergy syndrome, dysgeusia, cough, dry throat, dysphonia, dyspnoea, oropharyngeal pain, pharyngeal oedema, pharyngeal paraesthesia, abdominal pain, diarrhoea, dyspepsia, dysphagia, gastrooesophageal reflux disease, glossodynia, hypoaesthesia oral, lip oedema, lip pruritus, nausea, oral discomfort, oral mucosal blistering, stomatitis, swollen tongue, urticaria, chest discomfort, sensation of foreign body. **Unknown:** anaphylactic reaction, eosinophilic oesophagitis. 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 severe systemic or 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:** PA1255/007/001. **Updated:** June 2022. 2022-289TTIR

**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**