Produced and funded by ALK: For patients who have been prescribed ITULAZAX®

Your essential guide

ITULAZAX®

(*Betula verrucosa*, allergen extract, white birch pollen)

FOR PATIENTS AGED 5 AND OVER with moderate to severe allergic rhinitis and/or conjunctivitis caused by birch tree family pollen[1]*



***From birch, alder, hornbeam, hazel, oak, and beech trees[1]**

This guide has been created to give you helpful information on taking ITULAZAX®. Please read it alongside the Patient Information Leaflet (PIL) in the tablet packaging. If you have any questions or concerns, please speak to your healthcare professional.

ALK

Allergy solutions for life

Hello

If you've been prescribed ITULAZAX® for tree pollen allergy, this guide is for you.

It covers the information you'll need to get the most from your treatment and what to do if you experience any side effects.



ITULAZAX® can lead to[1]:

- Improvements in disease control and quality of life
- Symptom relief
- Reduced need for symptom-relieving medication

About ITULAZAX®

ITULAZAX® is used to treat patients 5 and over who have a positive test of sensitisation to any member of the birch homologous group[1], and are living with with moderate to severe symptoms – even when taking other symptom relieveing medications.[1]

ITULAZAX® is an allergen immunotherapy treatment (also known as AIT) that's taken orally. This means you take it by placing a pill under your tongue every day.[1]

ITULAZAX® is a sublingual lyophilisate, this means it is a fast dissolving[2] tablet you put under the tongue. It contains high quality, controlled amounts of birch tree pollen.[1] The idea is that repeated doses help your immune system to build a tolerance to tree pollen – that's the allergy immunotherapy bit.[1]

Easy to remember dosing

- You only need to take one tablet a day[1]
- If you miss a dose one day, don't take two tablets the next[1]
- Taking more than one tablet a day (overdosing) may be harmful and can cause severe allergic reactions[1]

Starting treatment

- Your medical team will explain any side effects (adverse reactions) and how to manage them
- Your first tablet should be taken under medical supervision in the clinic so you can be monitored for side effects[1]
- Your healthcare professional will monitor you for at least 30 minutes. They'll be able to identify, discuss and treat any side effects[1]
- Read the patient information leaflet inside the packaging and follow the instructions carefully
- Your treatment should have little or no impact on your ability to drive or operate machinery[1]

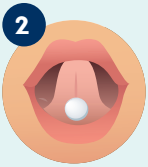
Starting treatment before the tree pollen season

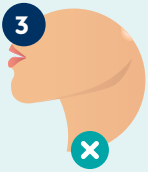
It's recommended that you begin your treatment with ITULAZAX® before the start of the tree pollen season (TPS) and continue it during the season.[1] Research has shown that improvements happen when patients begin treatment 16 weeks before the TPS.[1*]

* TPS in the UK = February (Alder) – June (Oak) (Source: Tree Pollen. AllergyUK/University of Worcester. 09 March 2021)

How to take ITULAZAX®[1]

1. 
Always use dry fingers to remove the tablet from the blister card

2. 
Immediately place the tablet under your tongue. It will dissolve quickly

3. 
Avoid swallowing for one minute

4. 
Don't eat or drink anything else for another five minutes

How ITULAZAX® works

Your birch tree pollen allergy is caused by your body's immune response to harmless tree pollen (the allergen).[3] That means your immune system has misidentified the pollen as a threat and is responding in unhelpful ways.[3] These responses are also known as hypersensitivities and lead to symptoms such as sneezing, a runny or blocked nose.[5]

ITULAZAX® is an allergen immunotherapy treatment (AIT), also sometimes known as desensitisation therapy.[1,3] By regularly exposing your body to highly standardized concentrations of the tree pollen allergen, it helps your body to build immunity.[3] Over time, this reduces your body's unhelpful responses, which in turn reduces your symptoms.[3]

During AIT, the immune system's response changes.[3] The changes are complex and take time to happen, but you should expect to see improvements in your symptoms in the tree pollen season after starting treatment.[1]

ITULAZAX® can lead to improvements in disease control and quality of life reflected by symptom relief and reduced need for symptom relieving medication[1].



Things to do[1]

Before taking ITULAZAX® for the first time, tell your medical team if:

- You're allergic (hypersensitive) to any of the substances in the ITULAZAX® tablet
- You have asthma
- You've previously had a severe allergic reaction to injection immunotherapy. It might mean you have an increased risk of a similar response to ITULAZAX®
- You have an autoimmune disorder (eg MS, IBD, Type 1 diabetes, rheumatoid arthritis, or lupus), or you have an immune defect, an immunodeficiency disorder or immunosuppression
- You have a mouth infection/inflammation/ulcer/wound, had recent dental work (eg a tooth removed) or lost a tooth
- You have a cancerous tumour (malignant neoplasm)
- You have heart disease
- You have problems swallowing (dysphagia) or indigestion (dyspepsia)
- You have a fish allergy
- You are about to be vaccinated
- You are pregnant

Tell your medical team immediately if:

- You experience a severe allergic reaction
- You are diagnosed with a heart disease
- You become pregnant
- You have an illness that affects your immune system
- Your asthma symptoms get worse and/or you're diagnosed with severe asthma
- You are diagnosed with cancer
- Your mouth becomes severely inflamed, if you lose a tooth, have a tooth removed or need other oral surgery – you'll need to stop taking ITULAZAX® treatment while your gum/mouth heals
- You have persistent gastric symptoms such as difficulty swallowing, acid reflux or indigestion

If you go more than **7 days** between doses, please **contact your medical team** for advice before restarting treatment.[1]



Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. In most cases, any side effects from your immunotherapy will start within 10 minutes of taking the tablet each day and last for under one hour.[1,4] These reactions are likely to be mild or moderate in severity and occur within the first few days of starting treatment.[1,4] Usually, they disappear within a few months, or even within a week or two.[1,4]

Stop taking ITULAZAX® and talk to your doctor or hospital immediately if you experience any of the following signs of a serious reaction:[4]

- Your asthma gets noticeably worse than normal
- Severe swelling of the throat
- Difficulty in swallowing
- Difficulty in breathing
- Changes in your voice (e.g. hoarseness)
- Low blood pressure (hypotension)
- Feeling of fullness in the throat

Here are some possible side effects you may experience:

Very Common (may affect more than1 in 10 people):

- Itching of the ears, mouth or tongue
- Swelling of the mouth
- Irritating sensation in the throat
- Prickling sensation of the mouth

Common (may affect up to 1 in 10 people):

- Runny nose
- Oral allergy syndrome (itching and/or swelling in the mouth and throat after eating certain raw vegetables, fruits or nuts)
- Altered taste
- Cough
- Dry throat
- Hoarseness
- Shortness of breath
- Pain in the mouth or throat
- Swelling of the throat
- Stomach pain
- Diarrhoea
- Heartburn
- Pain when swallowing or difficulty swallowing
- Painful or burning feeling of the tongue
- Numbness of the mouth
- Swelling of the lips or tongue
- Lip itching
- Nausea
- Mouth discomfort
- Blisters in the mouth
- Prickling sensation of the throat
- Inflammation in the mouth
- Hives
- Chest discomfort
- Sensation of something stuck in the throat

If any side effects are worrying you or causing you difficulties, you should contact your healthcare team.

Please refer to the patient information leaflet found inside the packaging for further details about side effects.

Report your side effects

If you have any side effects, talk to your healthcare professional. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly, via the Yellow Card Scheme, at **www.yellowcard.mhra.gov.uk** or at **www.hpra.ie (Ireland)**

By reporting side effects, you can help provide more information on the safety of this medicine.

Side effects should also be reported to ALK Medical Information on **drugsafetyuk@alk.net**



What to expect[1]

ITULAZAX® should improve your disease control and quality of life. You should experience symptom relief and reduced need to use other symptomrelieving medication.

Your doctor will stop your ITULAZAX® if you don't feel better during the first year of treatment.

Expect some mild to moderate local reactions. Most appear within 10 minutes of taking a tablet and fade within an hour. These should disappear after a few months or even **after a week or two**. Talk to your HCP to help you manage these[1].

Remember

1. ITULAZAX® can lead to improvements in how you feel during the tree pollen season[1].
2. Start ITULAZAX® treatment at least 16 weeks before the tree pollen season[1].
3. Continue to take one tablet daily for 3 years[1].
4. Manage side effects and evaluate the clinical benefits at the end of the season with your HCP
5. Take ITULAZAX® for 3 years to help change your body's response to tree pollens. Report any side effects[1].

References

1. ITULAZAX® Summary of Product Characteristics.
2. https://www.catalent.com/oral-dose/oral-technologies/orally-disintegratingtablets.
3. British Society for Immunology. Policy Briefing: Allergy. April 2017. Available at: https://www immunology.org/policy-and-public-affairs/briefings-and-position-statementsallergy
4. ITULAZAX® Patient Information Leaflet.
5. Biedermann et al 2021, The Journal of Allergy and Clinical Immunology: In Practice, Volume 9, Issue 5, Pages 1871-1878

ALK
Allergy solutions for life

GB-IZX-2400002 July 2025