

Your essential guide

ITULAZAX®▼
(allergen extract, white birch pollen)

For adult patients with moderate to severe allergic rhinitis and/or conjunctivitis caused by birch tree family pollen¹

**WHEN YOU CAN'T
CONTROL YOUR
SYMPTOMS**
with symptom
relieving medications,¹
allergy immunotherapy
tablets for everyday
use at home¹

¹From birch, alder, hornbeam, hazel, oak, or beech trees¹

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.



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.

Improving your quality of life:¹

- ✓ Relieve your symptoms
- ✓ Reduce the need for symptom-reducing medicines
- ✓ Control your disease
- ✓ Change how your body responds to tree pollen

About ITULAZAX®

ITULAZAX® is used to treat birch tree family pollen allergy in adults who are living with moderate to severe symptoms – even when taking other symptom relieving medications.¹

ITULAZAX® is an allergy 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 fast-dissolving² tablet containing 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 day¹
- If you miss a dose one day, don't take two tablets the next¹
- Taking more than one tablet a day (overdosing) may be harmful and can cause severe allergic reactions¹



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 effects¹



Your healthcare professional will monitor you for at least 30 minutes. They'll be able to identify, discuss and treat any side effects¹



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 machinery¹



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 unnecessary immune response to harmless tree pollen (the allergen).⁴ That means your immune system has misidentified the pollen as a threat and is responding in unhelpful ways.⁴ These responses are also known as hypersensitivities and lead to symptoms such as wheezing and coughing.⁴

ITULAZAX® is an allergy immunotherapy treatment (AIT), also sometimes known

as desensitisation therapy.^{1,4} By regularly exposing your body to carefully controlled amounts of the tree pollen allergen, it helps your body to build immunity.⁴ Over time, this reduces your body's unhelpful responses, which in turn reduces your symptoms.⁴

During AIT, the immune system's response changes.⁴ 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® leads to improvements in disease control and quality of life reflected by symptom relief and reduced need for symptom relieving medication.



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.^{1,5} These reactions are likely to be mild or moderate in severity and occur within the first few days of starting treatment.^{1,5} Usually, they disappear within a few months, or even within a week or two.^{1,5}

Stop taking ITULAZAX® and talk to your doctor or hospital immediately if you experience any of the following signs of a serious reaction:⁵

- 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
- Severe or persistent heartburn

Here are some possible side effects you may experience:

Very Common (may affect more than 1 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. They will decide if you need any medicines such as antihistamines to help relieve your side effects.

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.

▼ This medicine has a black triangle so is subject to additional monitoring. This helps to quickly identify new safety information.

Side effects should also be reported to ALK Medical Information on **0118 903 7940** or drugsafetyuk@alk.net

Things to do¹

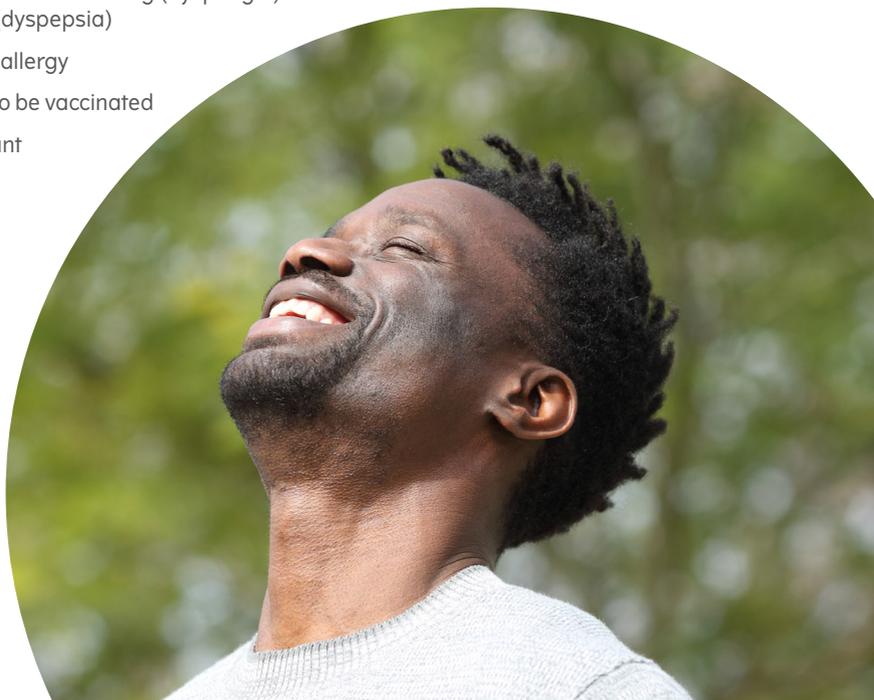
Before taking ITULAZAX® for the first time, tell your medical team if:

- ✔ You're allergic (hypersensitive) to any of the substances in the ITULAZAX® tablet
- ✔ You have previously been treated with immunotherapy injections and experienced a severe reaction
- ✔ 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





What to expect

ITULAZAX® should improve your disease control and quality of life. You should experience symptom relief and reduced need to use other symptom relieving medication during the tree pollen season.

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.



Remember

1. ITULAZAX® treats the underlying cause of your allergy not just your symptoms
2. Start ITULAZAX® treatment at least 16 weeks before the tree pollen season
3. Continue throughout the season
4. Manage side effects and evaluate the clinical benefits at the end of the season with your HCP
5. Take ITULAZAX® for 3 years aiming for disease modification. Report any side effects

References

1. ITULAZAX® Summary of Product Characteristics.
2. <https://www.catalent.com/oral-dose/oral-technologies/orally-disintegrating-tablets>.
3. ALK Data on File 2021-227C.
4. British Society for Immunology. Policy Briefing: Allergy. April 2017. Available at: <https://www.immunology.org/sites/default/files/Allergy%20briefing.pdf>.
5. ITULAZAX® Patient Information Leaflet.



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2021-231TT | October 2021