Therapeutics Advisory Group

Improving lives together
Norfolk and Waveney Integrated Care System

Prescribing Guidance - Betula verrucosa (Itulazax 12 SQ Bet) for treating moderate to severe allergic rhinitis or conjunctivitis caused by tree pollen

September 2025 v1.0

Itulazax® is used to treat moderate to severe allergic rhinitis or conjunctivitis caused by pollen from the birch homologous group of trees (birch, alder, hazel, hornbeam, oak, beech). It can be used for patients who have:

- Clinical history of symptoms despite use of symptom-relieving medication
- Positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE)'.

Treatment will be initiated by a clinician in the allergy clinic. They will monitor patient and provide medication for the first month. GP will be asked to prescribe thereafter.

AMBER - SPECIALIST INITIATION: Specialist Allergy Clinic to provide medication for the first month. GP to prescribe thereafter.

Background

Itulazax® can be used as an option to treat moderate to severe allergic rhinitis or conjunctivitis caused by pollen from the birch homologous group of trees in adults with:

- symptoms despite using symptom-relieving medicines
- a positive sensitisation test (skin prick test or specific immunoglobulin E) to a member of the birch homologous group

NICE has published guidance to support the use of Itulazax® - TA1087

Procedure

Treatment is initiated by an allergy specialist at least 4 months before the expected start of the tree pollen season. It should be continued all year round for a total of 3 years to obtain long-term effect. Specialist will review patient at the end of the pollen season. If symptoms have not improved, treatment may be stopped.

Itulazax® comes as a daily sublingual tablet. One or two hours before taking Itulazax®, patient should be advised to take an antihistamine.

The first Itulazax® dose will be administered in the allergy clinic to ensure that the tablet is taken correctly. Patient will be monitored for any side effects. Before initiation, patient will be asked to complete a consent form, and they will have pulse, blood pressure and peak expiratory flow rate (PEFR) checked.

Tablets must be taken out of the packet with dry fingers and placed under the tongue. Patient should avoid eating or drinking for at least 5 minutes to ensure the tablet is completely dissolved. They will be asked to remain in the department for at least one hour. They should be able to take subsequent doses at home.

A couple of days after starting the medication, patient will be asked to phone or email the allergy clinic to discuss treatment and to report any side effects or concerns. Adverse effects can also be reported via the Yellow Card scheme - https://yellowcard.mhra.gov.uk/

The specialist will review the patient after 4 months to confirm ongoing treatment. Patient's regular GP will be asked to continue to prescribe Itulazax®, as well as any rescue medication for breakthrough symptom relief, as advised by the specialist.

If treatment with Itulazax® is interrupted for a period of up to 7 days, treatment can be resumed by the patient. If the treatment is interrupted for more than 7 days, it is recommended to contact specialist for advice before resuming the treatment.

Side effects

Side effects may be an allergic response to the allergen (pollen) being treated. Most allergic side effects are mild to moderate and happen within the first few days of treatment. They should disappear within a few months, or in many cases within a week or two.

Very rarely, patients may experience potentially severe side effects including:

- Worsening asthma
- Severe swelling of the throat
- Difficulty in swallowing or breathing
- Changes in voice (e.g. hoarseness)
- Low blood pressure (hypotension)
- Feeling of fullness in the throat

If any of these symptoms occur, patient should stop treatment and seek medical help immediately by calling 999 or going to local Accident and Emergency department.

For any other non-urgent symptoms patient should inform the allergy clinic or GP/Pharmacist.

Contraindications

It is important that patient continues prescribed medications, including medication to treat hay fever, asthma and other allergic conditions. They should be advised to inform the allergy clinic if their medications change before or after initiation of treatment.

Itulazax® is contraindicated in the following:

- Patients with FEV_1 <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 prior to initiation.
- Patients with uncontrolled asthma within the last 3 months prior to initiation.
- Patients with active systemic autoimmune disorders (unresponsive to treatment) and patients with immune defects, immunodeficiencies or immunosuppression.
- Patients with malignant neoplasia with current disease relevance.
- Patients with acute severe oral inflammation or oral wounds

Special Care and Vaccinations

Itulazax® is not intended for use in children below 5 years of age. Experience in elderly (65 years and older) is limited.

Rare cases of serious anaphylactic reactions have been reported. Therefore, medical supervision at start of treatment is an important precaution. In some cases, the reaction has occurred after the initial dose.

Serious anaphylactic reactions may be treated with adrenaline. Consider whether your patient would be able to tolerate adrenaline:

- Effects of adrenaline may be increased in patients treated with tricyclic antidepressants, mono amino oxidase inhibitors (MAOIs) and/or COMT inhibitors
- Effects of adrenaline may be reduced in patients treated with beta-blockers.

The onset of systemic symptoms may include flushing, pruritus, sense of heat, general discomfort and agitation/anxiety.

Patients with cardiac disease or asthma may be at increased risk of severe systemic allergic reactions.

In patients with severe oral inflammation, oral wounds or following oral surgery, initiation should be postponed and ongoing treatment should be temporarily interrupted to allow healing of the oral cavity.

Cases of eosinophilic oesophagitis have been reported in association with Itulazax® treatment. In patients with severe or persistent gastro-oesophageal symptoms such as dysphagia or dyspepsia, Itulazax®X should be interrupted, and medical evaluation must be sought.

Itulazax may contain traces of fish protein. Data does not show increased risk of reaction in patients with fish allergy.

Vaccinations may be given without interrupting treatment, although patient should be reviewed first. Allergy clinic should be informed if vaccinations are planned.

Pregnancy and breastfeeding

Pregnancy

There is no data on the clinical experience for the use of Itulazax® in pregnant women. Animal studies do not indicate increased risk to the foetus. Treatment should not be initiated during pregnancy. If pregnancy occurs during treatment, the treatment may continue after evaluation of the general condition (including lung function) of the patient and reactions to previous administration of Itulazax®. In patients with pre-existing asthma, close supervision during pregnancy is recommended.

Breastfeeding

There is no clinical data available for the use of Itulazax® during lactation. No effects on the breastfed infants are anticipated.

Fertility

There is no clinical data with respect to fertility for the use of Itulazax®. In a repeat dose toxicity study in naïve mice, no effects were observed in the reproductive organs of both genders.

Summary Table

Stage of Treatment	Allergy Clinic	General Practitioner
Initiation	• Pre-treatment questionnaire. Following assessment and written consent, first tablet given under supervision. Patient observed for a minimum of 1 hour. • Once stable, transferred to maintenance dose of 1 tablet daily, self-administered at home. • First month to be prescribed by specialist. • Letter to GP advising date of commencement and relevant information • Clinic contact details provided to patient.	• GP to prescribe after first month treatment. • GP to prescribe any rescue medication for break through symptom relief, as advised by specialist.
Review	• Specialist review at 4–6 months post-initiation. • Treatment should be stopped if insufficient benefit is observed.	• GP to be informed by specialist regarding continuation.
Maintenance	• Further annual assessment and review by clinic during 3-year course of treatment. • Advise GP for end date for treatment.	• GP to prescribe for remainder of 3-year course and any symptomatic treatment.

Adapted for local use from guidance published by:

- ITULAZAX 12 SQ-Bet - Summary of Product Characteristics (SmPC) - (emc) | 12906 – accessed 30/9/2025
- Overview | Betula verrucosa for treating moderate to severe allergic rhinitis or conjunctivitis caused by tree pollen | Guidance | NICE – accessed 30/9/2025

Title	Prescribing Guidance - **Betula verrucosa (Itulazax 12 SQ Bet) for treating moderate to severe allergic rhinitis or conjunctivitis caused by tree pollen.**
Description of policy	To inform healthcare professionals
Scope	Norfolk and Waveney Integrated Care System
Prepared by	Norfolk and Waveney ICB Medicines Optimisation Team
Impact Assessment (Equalities and Environmental)	Please indicate impact assessment outcome: Positive impact Adverse impact - low - action plan completed as per guidance Adverse impact - medium - action plan completed as per guidance Adverse impact - high - action plan completed as per guidance No impact **No policy will be approved without a completed equality impact assessment**
Other relevant approved documents	Formulary application presented to TAG for Itulazax
Evidence base / Legislation	Level of Evidence: A. based on national research-based evidence and is considered best evidence **B. mix of national and local consensus** C. based on local good practice and consensus in the absence of national research-based information.
Dissemination	Is there any reason why any part of this document should not be available on the public web site? ☐ Yes / No ☒
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1.0	Specialist I+F Technician, NWICB	New document to support prescribers with SLIT	Sept 2025