

ITULAZAX®



Package leaflet: Information for the user

ITULAZAX 12 SQ-Bet, oral lyophilisate For use in adults

Standardised allergen extract of pollen from white birch (*Betula verrucosa*)

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ITULAZAX is and what it is used for
2. What you need to know before you take ITULAZAX
3. How to take ITULAZAX
4. Possible side effects
5. How to store ITULAZAX
6. Contents of the pack and other information

1. What ITULAZAX is and what it is used for

What ITULAZAX is

ITULAZAX contains an allergen extract of birch pollen. It comes in a form known as a oral lyophilisate, which is like a tablet but much softer and absorbed into the body by putting it under the tongue.

What ITULAZAX is used for

Treatment of:
- 'allergic rhinitis' and/or
- 'conjunctivitis'
when these are caused by tree pollen from birch, alder, hazel, hornbeam, oak and beech trees.

- 'Allergic rhinitis' is where the inside of the nose is inflamed – making you sneeze or have a stuffy or runny nose.
- 'Conjunctivitis' is where the eyes are inflamed – making them red, itchy or watery.

ITULAZAX is used in adults.

ITULAZAX is prescribed by doctors with experience in treating allergies.

How ITULAZAX works

Itulazax works by increasing the immunological tolerance (your body's ability to cope) to tree pollen.

How the doctor will decide if ITULAZAX is suitable for you

The doctor will check your allergic signs and do a skin prick test and/or take a blood sample.

2. What you need to know before you take ITULAZAX

Do not take ITULAZAX if:

- You are allergic to any of the other ingredients of this medicine (listed in section 6).
- You have poor lung function – your doctor will decide this.
- You have had a severe asthma worsening or uncontrolled asthma episodes within the last 3 months – your doctor will decide this.
- You have an illness that affects the immune system, are taking medicine that suppress the immune system or have cancer.
- You have recently had a tooth taken out, other forms of mouth surgery, or have mouth ulcers or mouth infections. Your doctor may recommend delaying the start of the treatment or stopping treatment until your mouth has healed.

Warnings and precautions

Talk to your doctor before taking ITULAZAX if:

- You are being treated for depression with tricyclic antidepressants, mono amino oxidase inhibitors (MAOIs) or for Parkinson's disease with COMT inhibitors.
- You have a heart disease and/or you are being treated with beta-blockers.
- You have previously had a severe allergic reaction to an injection of allergen extract of tree pollen.
- You have asthma and an ongoing airway infection, such as common cold, sore throat or pneumonia, on the day you are to take the first dose of ITULAZAX - your doctor will delay the start of your treatment until you are better.
- You have had a severe asthma exacerbation within the last 12 months

- You have an illness that affects the immune system or are taking medicines that suppress the immune system.
 - You are being vaccinated. Your doctor will decide if you can be vaccinated without interrupting treatment with ITULAZAX.
 - You have allergies to fish. ITULAZAX may contain traces of fish protein. Available data have not indicated an increased risk of allergic reactions in patients with a fish allergy.
- Talk to your doctor before taking ITULAZAX if any of the above apply to you.

You should stop taking ITULAZAX and contact your doctor, if you experience severe or persistent heartburn or difficulty in swallowing, as these symptoms could be signs of allergic inflammation of the oesophagus.

ITULAZAX contains the pollen that you are allergic to – so you can expect some mild to moderate allergic reactions. These reactions may be in the mouth and throat. If they are troublesome, talk to your doctor to see if you need any anti-allergic medicines such as antihistamines. You may experience new allergic reactions on the first few days of at-home treatment, which were not observed on the first day of treatment at the doctors surgery. See section 4 for information about possible side effect.

Children and adolescents

ITULAZAX is not intended for use in children or adolescents.

Other medicines and ITULAZAX

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you are taking other medicines for your allergy symptoms such as antihistamines or corticosteroids, your doctor should evaluate the use of such medicines. If you stop taking these medicines for your allergy symptoms you may experience more side effects of ITULAZAX.

ITULAZAX with food and drink

Do not eat or drink for at least 5 minutes after taking the medicine.

Pregnancy, breast-feeding and fertility

There is no experience with the use of ITULAZAX during pregnancy. Treatment with ITULAZAX should not be started during pregnancy. If you become pregnant during treatment, talk to your doctor about whether it is appropriate for you to continue the treatment.

There is no experience with the use of ITULAZAX during breast-feeding. However, no effects on the breast-fed babies are anticipated. Talk to your doctor about whether you may continue to take ITULAZAX while breast-feeding your baby.

There is no experience with the use of ITULAZAX when you are planning to have a baby. Talk to your doctor for advice before taking this medicine if you are planning to have a baby.

Driving and using machines

ITULAZAX has no or very little effect on the ability to drive or use machines. However, only you can judge if you feel that your ability is affected, therefore, if you are unsure, please talk to your doctor or pharmacist.

3. How to take ITULAZAX

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much ITULAZAX to take

- The recommended dose is one oral lyophilisate (soft tablet) daily.

How to take ITULAZAX

Start taking ITULAZAX at least 4 months before the expected start of the tree pollen season - your doctor will tell you how long you should take ITULAZAX for. It is recommended to continue ITULAZAX treatment for 3 years to obtain long-term effect.

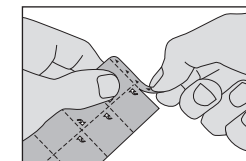
The first dose of ITULAZAX should be taken at the doctors surgery.

- This is because you should stay under medical observation for at least half an hour after taking the first dose.
- This is a precaution to check your sensitivity to the medicine.
- This will also give you the chance to discuss with the doctor, any possible side effects you may have.

Keep taking ITULAZAX every day - even if it takes some time before your allergy improves.

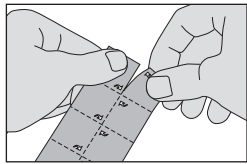
Make sure your hands are dry before handling the medicine.

Take the medicine like this:

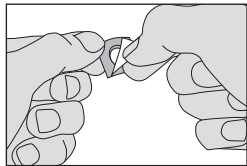


1. Tear off the strip marked with triangles at the top of the pack.

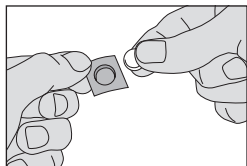




2. Tear a square off the pack along the dotted lines.



3. Fold back the marked corner of the foil and then pull it off.
- Do not force the medicine through the foil – as it breaks easily.



4. Remove the medicine carefully from the foil and place it under your tongue straight away.



5. Keep the medicine under your tongue until it has dissolved.
- Do not swallow for 1 minute.
- Do not eat or drink for at least 5 minutes after taking the medicine.

Use in children and adolescents

ITULAZAX is not intended for use in children or adolescents.

Use in elderly

Experience in elderly (65 years and older) is limited.

If you take more ITULAZAX than you should

If you take more ITULAZAX than you should, you are more likely to get allergic side effects – such as those in the mouth and throat. If you get severe side effects, contact a doctor or a hospital immediately. See section 4.

If you forget to take ITULAZAX

- If you forget to take a dose of ITULAZAX, take it later in the same day.
- Do not take a double dose on any one day to make up for a forgotten dose.
- If you have not taken ITULAZAX for more than 7 days, talk to your doctor before taking ITULAZAX again.

If you stop taking ITULAZAX

If you do not take this medicine as you have been told, you may not get the benefits.
If you have any questions on the use of this medicine, talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects may be an allergic response to the allergen (pollen) you are being treated with.

- 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.

If they are worrying you or causing you difficulties, talk to your doctor who will decide if you need any anti-allergic medicines such as antihistamines.

If you have side effects, they typically start within 10 minutes after taking ITULAZAX on each day of taking the medicine - and decrease within an hour.

Serious side effects:

Not known (frequency cannot be estimated from available data):
- Serious allergic reaction

Stop taking ITULAZAX and talk to your doctor or hospital immediately if you experience any of the following:

- Signs of a serious allergic reaction:
 - 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

Other side effects:

- 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
- Eye symptoms (e.g. itching, tearing, swelling, redness)
- 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

Uncommon (may affect up to 1 in 100 people):

- Tightness in the throat
- Inflammation of the tongue
- Lip blistering
- Mouth ulcers
- Irritation of the oesophagus
- Rapid swelling of the face, mouth or throat

Not known (frequency cannot be estimated from available data):

- Allergic inflammation of the oesophagus (eosinophilic oesophagitis)

If any side effects are worrying you or causing you difficulties, talk to your doctor who will decide if you need any other medicines such as antihistamines to help relieve the side effects.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the HPRA via HPRA Pharmacovigilance; Website www.hpra.ie.

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

5. How to store ITULAZAX

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after 'EXP'. The expiry date refers to the last day of that month.

Store in the original blister in order to protect from moisture. This medicinal product does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ITULAZAX contains

The active substance is standardised allergen extract of pollen from white birch (*Betula verrucosa*). The activity per oral lyophilisate is expressed using the unit SQ-Bet. The activity of one oral lyophilisate is 12 SQ-Bet.

The other ingredients are gelatine (from fish), mannitol and sodium hydroxide (for pH adjustment).

What ITULAZAX looks like and contents of the pack

White to off-white circular oral lyophilisate marked with a debossed image on one side.

Aluminium blister cards with removable aluminium foil in an outer carton. Each blister card contains 10 oral lyophilisates.

Following pack sizes are available: 30 or 90 oral lyophilisates.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

ALK-Abelló A/S
Bøge Allé 6-8
2970 Hørsholm
Denmark

Manufacturer

ALK-Abelló S.A.
Miguel Fleta 19
28037 Madrid
Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Ireland, Luxembourg, Netherlands, Norway, Poland, Romania, Slovakia, Slovenia and Sweden: ITULAZAX

This leaflet was last revised in February 2022.

