

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ITULATEK®

Standardized Allergen Extract, White Birch (*Betula Verrucosa*)

Sublingual Tablet, 12 SQ-Bet

Read this carefully before you start taking ITULATEK® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ITULATEK®.

Serious Warnings and Precautions

- ITULATEK® is intended for use only by doctors with adequate training and experienced in the treatment of allergic diseases.
- It is common for patients to experience mild or moderate local allergic reactions with ITULATEK® (for example, an itchy mouth or a sore throat). Serious life-threatening allergic reactions which require immediate medical attention may occur in patients treated with ITULATEK®. If you experience stronger allergic reactions with a feeling of tightness or swelling in the throat, difficulty swallowing or breathing and voice changes, contact your physician immediately. The treatment has to be stopped immediately until your physician advises otherwise.
- The first tablet of ITULATEK® must be taken at the doctor's office. Your doctor will also tell you to stay on site for 30 minutes to check out for possible side effects to the treatment you may have.

What is ITULATEK® used for?

ITULATEK® is for adults aged 18 to 65 who are allergic to tree pollen from birch, alder and/or hazel and have allergic rhinitis (with or without conjunctivitis). Symptoms of allergic rhinitis include sneezing, runny or itchy nose, stuffed up nose (with or without symptoms of conjunctivitis such as itchy, burning, red, or watery eyes).

Before you begin treatment with ITULATEK®, your allergy to tree pollen will be confirmed by a doctor who will perform skin and/or blood tests.

ITULATEK® is NOT a medication that gives immediate relief for symptoms of tree pollen allergy.

ITULATEK® has not been tested in patients younger than 12 years or older than 65 years of age. The efficacy and safety of ITULATEK® have not been established in subjects between the ages of 12 and 18.

How does ITULATEK® work?

ITULATEK® is a tablet that treats your allergy caused by tree pollen from birch, alder and/or hazel. It contains a birch pollen allergen extract that helps to make you less sensitive to the tree pollen you are

allergic to.

What are the ingredients in ITULATEK®?

Medicinal ingredients: Standardized Allergen Extract, White Birch (*Betula verrucosa*).

Non-medicinal ingredients: fish gelatin, mannitol and sodium hydroxide. ITULATEK® does not contain lactose.

ITULATEK® comes in the following dosage forms:

ITULATEK® is a prescription tablet that you take once a day by placing it under your tongue.

Each tablet contains 12 SQ-Bet of a Standardized Allergen Extract, White Birch (*Betula verrucosa*).

Do not use ITULATEK® if:

- you are allergic (hypersensitive) to any of the non-medicinal ingredients of ITULATEK® (see **What are the ingredients in ITULATEK®?**)
- you have had a serious allergic reaction to tree pollen allergy shots, tablets or drops
- you have severe or unstable asthma
- you are taking beta-blockers (a medicine prescribed for heart conditions, such as high blood pressure)
- you have any swelling or sores in your mouth or have recently had any mouth injury or mouth surgery (such as a tooth removal). Your doctor may delay the start of your treatment until you are better
- you have a history of eosinophilic esophagitis

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ITULATEK®. Talk about any health conditions or problems you may have, including if you:

- have worsening asthma symptoms or breathing problems
- have an airway infection, such as common cold, sore throat or pneumonia on the day you are to take the first dose of ITULATEK® - your doctor may delay the start of your treatment until you are better
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed. It is not known if ITULATEK® will pass into breast milk
- are being treated for depression with tricyclic antidepressants, mono amino oxidase inhibitors (MAOIs) or for Parkinson's disease with COMT inhibitors
- have a heart disease and/or you are being treated with beta-blockers
- are being vaccinated. Your doctor will decide if you can be vaccinated without interrupting treatment with ITULATEK®
- have an illness that affects the immune system, are taking medicine that suppress the immune system or have certain cancers

Other warnings you should know about:

There is limited experience with ITULATEK® in patients younger than 18 or older than 65. Therefore, the use of ITULATEK® is not recommended in these age groups.

Stop treatment and get emergency medical treatment right away if you have any of the following symptoms after taking ITULATEK®:

- dizziness, fainting, fast or weak heartbeat, feeling nervous or feeling of “impending doom”
- throat tightness or swelling of the tongue or throat that causes trouble speaking, breathing or swallowing
- wheezing, shortness of breath, cough, chest tightness or trouble breathing
- stomach cramps, vomiting or diarrhea
- skin rash, itching, flushing or hives

Stop treatment with ITULATEK® if you have any of the following symptoms that do not go away or that worsen:

- heartburn, difficulty swallowing, pain with swallowing, or chest pain

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines. Your doctor will tell you if it is safe to take other medicines while you are using ITULATEK®. **No drug interaction studies have been done in patients taking ITULATEK®.**

How to take ITULATEK®:

The first dose of ITULATEK® should only be taken in the doctor’s office. After taking the first dose, you will be watched for 30 minutes by a healthcare professional for symptoms of a serious allergic reaction.

Your doctor may prescribe medicines for you to take in case you have a serious allergic reaction.

After the first dose, you may take ITULATEK® at home.

Usual dose:

Take ITULATEK® once daily for as long as your doctor tells you to take it, usually until at least the end of the yearly tree pollen season. For symptom improvement during the first tree pollen season, you should start taking ITULATEK® at least 16 weeks before the tree pollen season usually begins.

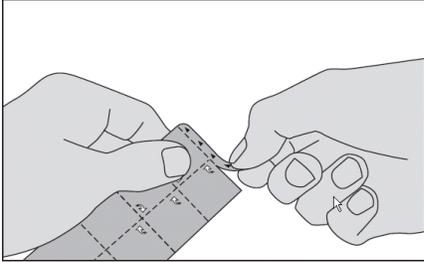
How should I take ITULATEK®?

1. Do not use food or water to take the tablet
2. Remove the tablet from the package with dry hands by carefully removing the foil. (If your hands are wet or damp, the tablet will break or dissolve too soon)
3. Place the tablet under the tongue right away. It will rapidly dissolve

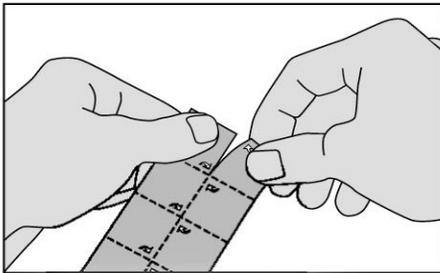
4. Do not swallow for about 1 minute
5. Do not drink or eat for 5 minutes after taking the tablet
6. Wash your hands after handling the tablet

Detailed Instructions

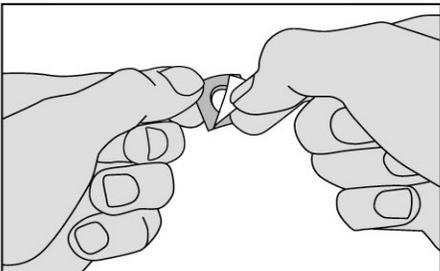
1. Tear off the strip marked with triangles at the top of the blister pack.

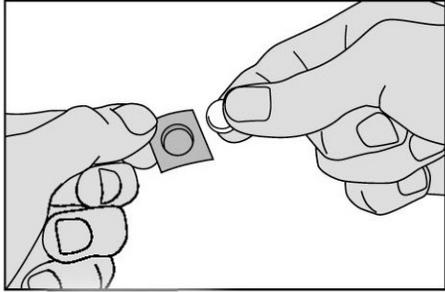


2. Tear a square off the blister pack along the perforated lines.



3. Remove the tablet carefully from the foil (*do not force the tablet through the foil. It may become damaged as it easily breaks. Instead, fold back the marked corner of the foil and then pull it off*). Take it immediately.





4. Place the tablet under the tongue. Allow it to remain there for a few seconds until it dissolves. Do not swallow during the first minute. Do not eat or drink for 5 minutes. Wash hands after handling the tablet.



General information about the safe and effective use of ITULATEK®

This medicine has been prescribed for you. Do not give it to anyone else. It may harm them, even if their symptoms are the same as yours.

Your doctor may also prescribe medications to treat possible allergic reactions from ITULATEK® treatment.

Overdose:

Taking more than one ITULATEK® tablet in one day can cause severe allergic reactions.

If you think you, or a person you are caring for, have taken too much ITULATEK®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Do not take more than one ITULATEK® tablet daily. If you miss a dose, return to your normal schedule the next day. Do not take a double dose to make up for the forgotten dose.

What are possible side effects from using ITULATEK®?

These are not all the possible side effects you may have when taking ITULATEK®. If you experience any side effects not listed here, tell your healthcare professional.

Side effects caused by ITULATEK® usually happen early in treatment, but can happen even if you have been taking ITULATEK® for months.

The most common side effects of ITULATEK® include:

- itching of the ears, mouth, tongue
- swelling of the mouth, tongue and lips
- cough or swelling in the throat
- painful or irritated throat
- numb or prickling sensation in the mouth

If you experience the following symptoms, contact your doctor immediately and get emergency treatment. Do not take any more doses until your doctor tells you to:

- swelling of the throat, mouth or tongue
- difficulty swallowing or breathing
- asthma attack/wheezing
- hives/itchy rash
- voice changes (hoarse voice or trouble speaking)
- rapid heart rate
- low blood pressure
- fainting

Side effects reported by adolescents and adults who were treated with ITULATEK® include:

Very common [in more than 10% of patients (1 in 10)]:

Mouth: itching, swelling, prickling sensation

Tongue: itching

Throat: irritation

Ear: itching

Common [in 1-10% of patients (more than 1 in 100 but less than 1 in 10)]:

Mouth: dryness, oral allergy syndrome (itching and/or swelling in the mouth and throat after eating certain raw foods), altered taste, pain, numbness, discomfort, blisters, inflammation

Tongue: swelling, pain or burning feeling

Lips: swelling, itching

Throat: dryness, pain, swelling, pain when swallowing or difficulty swallowing, prickling sensation

Eye: inflammation, tear flow, itching

Other: runny nose, cough, hoarseness, shortness of breath, heartburn, hives, sensation of something stuck, nausea

Uncommon [between 0.1% and 1% of patients (more than 1 in 1000 but less than 1 in 100)]:

Mouth: ulcers

Tongue: inflammation

Lips: blistering

Throat: swelling, tightness

Other: irritation of the oesophagus, rapid swelling of face, mouth and throat, abdominal pain upper

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

Eosinophilic esophagitis (EoE) which may present as any of the following symptoms that do not go away or worsen: heartburn, difficulty swallowing, pain with swallowing, or chest pain.

| Serious side effects and what to do about them | | | |
|------------------------------------------------|--------------------------------------|--------------|-------------------------------------------------|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| VERY COMMON Swelling in the mouth | √ | | |
| COMMON Difficulty swallowing | | | √ |
| Hives all over your body | | | √ |
| Sensation of something stuck in the throat | √ | | |
| Swelling in the throat | | √ | |
| Swollen tongue | √ | | |
| Oral allergy syndrome | √ | | |
| UNCOMMON Chest discomfort | √ | | |
| Rapid swelling in the face, mouth or throat | | | √ |
| Throat tightness | | | √ |
| RARE Severe allergic reaction | | | Seek emergency help immediately |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature (15 to 30°C)
- Store in the original blister to protect from moisture
- Do not use beyond the expiry date on the label
- Keep out of reach and sight of children.

If you want more information about ITULATEK®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:
(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>).
- Contact regarding reporting of Side Effects to ALK Inc.:
Telephone (toll-free): 1-800-325-7354 (for English) or 1-800-663-0972 (for French)
Fax (toll-free): 1-866-255-2244

This leaflet was prepared by ALK-Abelló A/S.

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