



ITULATEK®

Standardized Allergen Extract,
White Birch (*Betula Verrucosa*)
Sublingual Tablet, 12 SQ-Bet



**Your guide to using ITULATEK® for the treatment
of allergies to birch, alder, and/or hazel tree pollen.**

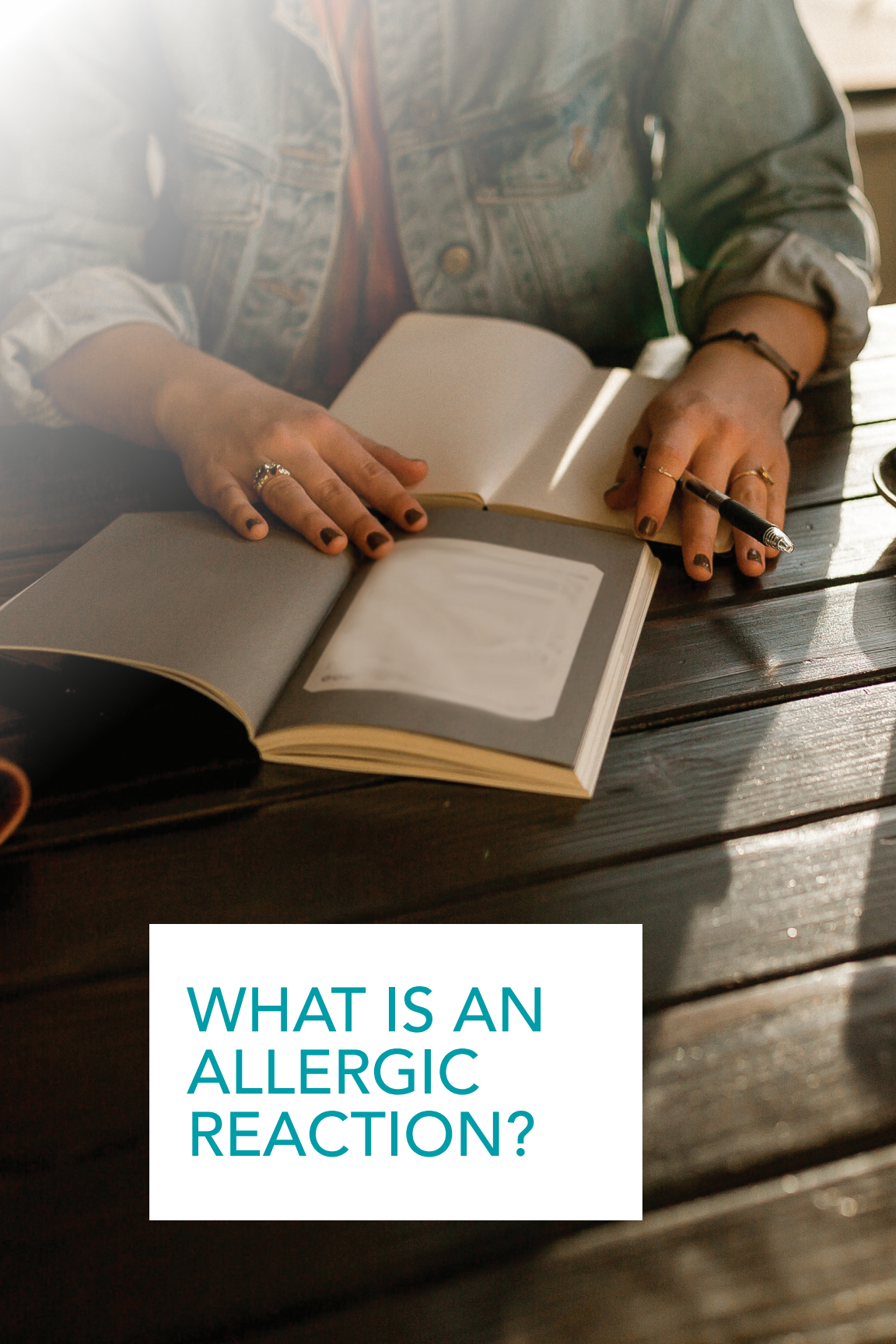
IMPORTANT:

See **page 6** for what ITULATEK® does
See **pages 8–10** for how to take ITULATEK®

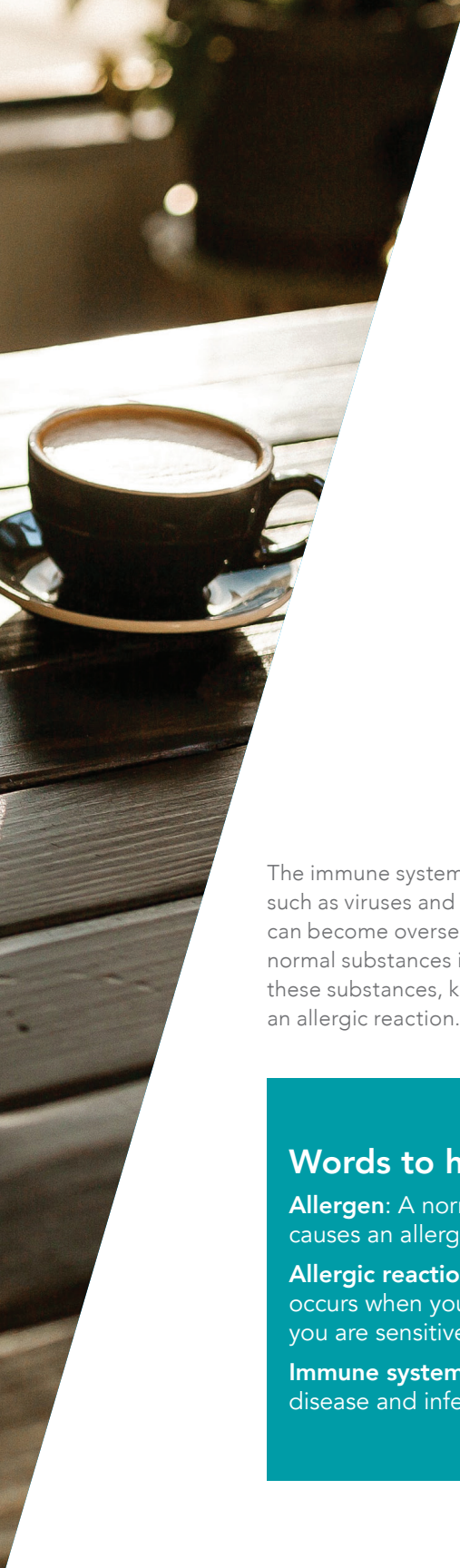


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WHAT IS AN
ALLERGIC
REACTION?



The immune system's job is to protect your body from invaders, such as viruses and bacteria. In some people, the immune system can become oversensitive. When this happens, the body thinks that normal substances in the environment are harmful. Upon contact with these substances, known as allergens, the immune system produces an allergic reaction.

Words to help with this section:

Allergen: A normal substance in the environment that causes an allergic reaction in people who are sensitive to it.

Allergic reaction: A reaction of the immune system that occurs when your body comes in contact with substances you are sensitive to.

Immune system: A system that protects your body from disease and infections.

WHAT IS BIRCH ALLERGY?

You may already know the answer to this question. However, you may want to explain the cause of birch allergy to your family or others. If so, we hope that you find the following helpful.

Birch trees release a powdery substance, called pollen. Breathing in tree pollen can cause allergy symptoms in those who are hypersensitive to birch pollen. These **symptoms may differ from person to person**, depending on how the body responds to birch pollen allergen.

Because the pollen of birch, alder, and hazel trees is very similar, **people who are allergic to 1 of them tend to be allergic to all 3.**

Symptoms of birch tree pollen allergy can **start during late January in Western Canada and during late March in Eastern Canada.** The season usually ends in late June.



1. Birch tree pollen is released by birch trees and travels in the air
2. Birch tree pollen can enter your body through your nose and mouth
3. The immune cells in the lining of your nose, mouth, and throat react to the allergen, causing the signs and symptoms of birch tree allergy

WHAT ARE THE SYMPTOMS OF BIRCH ALLERGY?

If you have a birch allergy, you probably know some of the symptoms that can occur when you come in contact with birch pollen. For example, when you are outside during tree pollen season, you may notice your eyes begin to water and your nose may get runny.

THE MOST COMMON SYMPTOMS OF BIRCH ALLERGY INCLUDE:

- Runny nose
- Itchy nose and eyes
- Sneezing
- Watery eyes
- Red eyes
- Nasal congestion



WHAT IS ITULATEK®?

ITULATEK® is a sublingual allergy tablet that contains an allergen extract used to help treat your allergies caused by birch, alder, and/or hazel trees, characterized by rhinitis with or without conjunctivitis.

ITULATEK® is to be prescribed only by doctors who are trained and experienced in the treatment of allergic diseases.

ITULATEK® reduces symptoms by helping to make you less sensitive to the birch, alder, and/or hazel tree pollens you are allergic to.

WHO IS ITULATEK® FOR?

ITULATEK® is used for the treatment of adults 18 to 65 years of age with a history of allergy to birch, alder, and/or hazel tree pollen. It has not been tested in patients younger than 12 years or older than 65 years of age.

You should not take ITULATEK® if you:

- Are allergic (hypersensitive) to any of the non-medicinal ingredients of ITULATEK®
- Have had a serious allergic reaction to tree pollen allergy shots, tablets, or drops
- Have severe or unstable asthma
- Are taking beta-blockers (a medicine prescribed for heart conditions, such as high blood pressure)
- 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
- Have a history of eosinophilic esophagitis

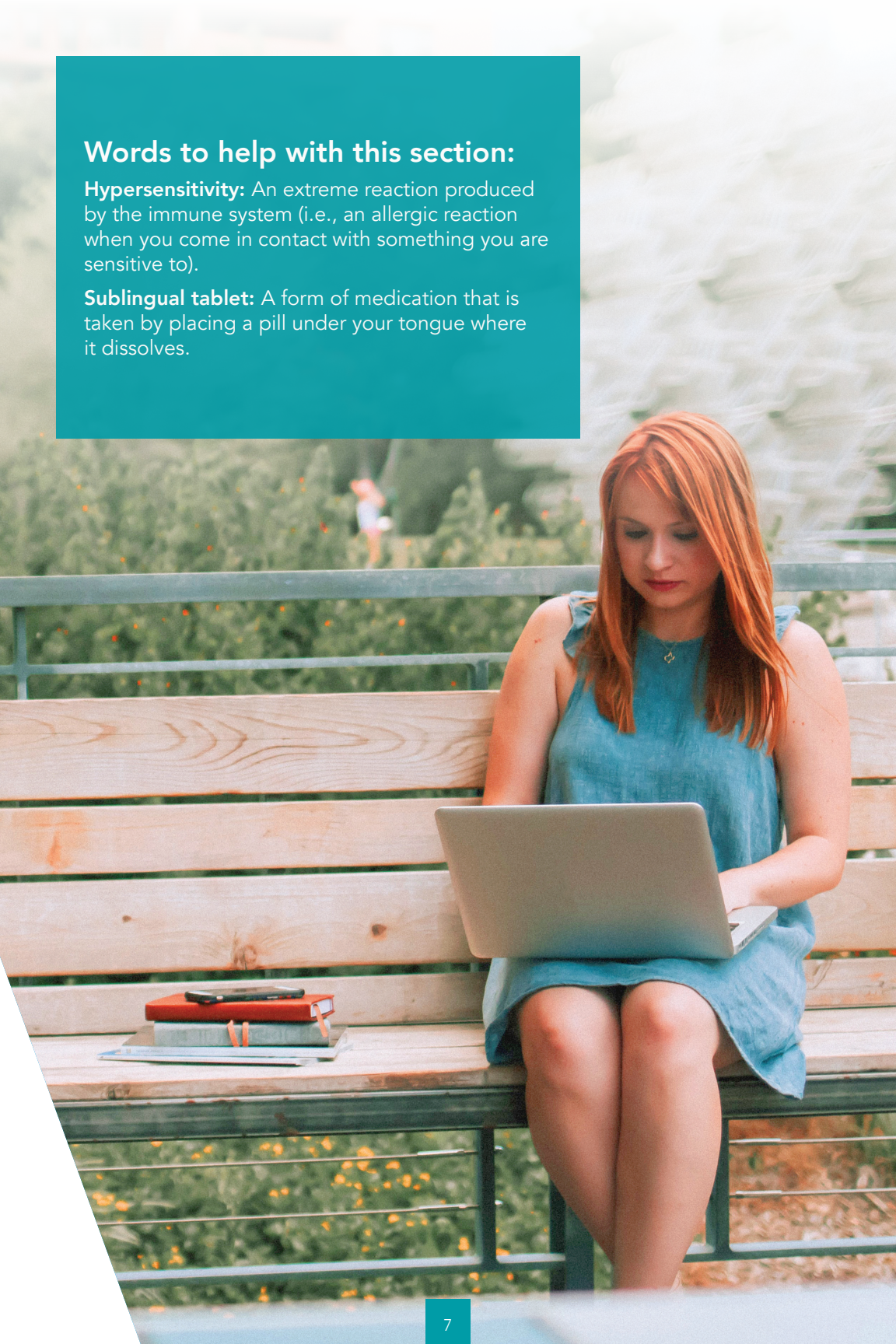
WHAT ARE THE INGREDIENTS IN ITULATEK®?

- The active ingredient in ITULATEK® is Standardized Allergen Extract, White Birch (*Betula verrucosa*)
- ITULATEK® does not contain lactose
- The other non-medicinal ingredients in ITULATEK® include: fish gelatin, mannitol and sodium hydroxide

Words to help with this section:

Hypersensitivity: An extreme reaction produced by the immune system (i.e., an allergic reaction when you come in contact with something you are sensitive to).

Sublingual tablet: A form of medication that is taken by placing a pill under your tongue where it dissolves.



HOW DO I TAKE ITULATEK®?

ITULATEK® should be taken **once a day** as one tablet of 12 SQ-Bet for as long as your doctor tells you to take it. Usually, this will be until at least the end of the birch, alder, and/or hazel pollen season.

The first dose of ITULATEK® should only be taken in the doctor's office:

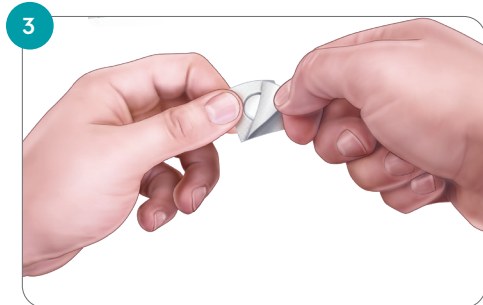
- **After taking the first dose, you will be watched for 30 minutes by a healthcare professional for symptoms of a serious allergic reaction**

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

Your doctor will start you on ITULATEK® **at least 16 weeks before birch, alder, and/or hazel tree pollen season** (whichever comes first) usually begins. After the first dose, you may take ITULATEK® at home.



ARE THERE SPECIAL INSTRUCTIONS FOR TAKING ITULATEK®?



Do not use food or water to take the tablet.

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 from the package with dry hands by carefully removing 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 right away.

4. **Place the tablet under the tongue** and allow it to remain there for a few seconds until it dissolves

Do not swallow during the first minute and do not eat or drink for 5 minutes.

Wash your hands after handling the tablet.

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.

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What if I miss a dose?

If you miss a dose, return to your normal schedule the next day. Do not take a double dose to make up for the missed dose.

What if I take too much?

Taking more than one ITULATEK® tablet in one day can cause severe allergic reactions. If you take too much, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

How do I store ITULATEK®?

- ITULATEK® should be stored at room temperature (15° to 30 °C)
- You should store ITULATEK® in its original package
- Keep package and tablets dry
 - Medicines should not be kept in a bathroom or kitchen cabinet
- Keep out of reach and sight of children

WHAT SHOULD I TELL MY DOCTOR BEFORE OR AFTER TAKING ITULATEK®?

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

Tell your doctor and pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Your doctor will tell you if it is safe to take other medicines while you are using ITULATEK®. However, no drug interaction studies have been done in patients taking ITULATEK®.

Before you take ITULATEK®, tell your doctor if you:

- Have ever had a serious allergic reaction to allergy shots or tablets
- Have worsening asthma symptoms or breathing problems
- Have an airway infection, such as common cold, sore throat or pneumonia
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed. It is not known if ITULATEK® will pass into breast milk
- Have diseases affecting the immune system e.g. autoimmune diseases, immune complex diseases or (severe) immune deficiency diseases
- Have malignant diseases (e.g. cancer)



WHAT ARE THE SIDE EFFECTS WITH ITULATEK®?

Like all medicines, ITULATEK® can cause side effects, although not everybody gets them. The side effects usually happen early in treatment and go away on their own. They may also happen after taking later doses. ITULATEK® may also cause serious allergic reactions, which can be life-threatening.

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

Uncommonly, stronger allergic reactions to ITULATEK® can occur. If you have any of the following symptoms, stop treatment and get emergency medical treatment right away:

- 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

In Clinical Study TT-04, subjects in active and placebo arms of this trial were allowed to take symptom-relieving allergy medications (including oral and ocular antihistamines and nasal corticosteroids) as needed.



Serious side effects: how often they happen 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	✓		
	Chest discomfort	✓		
Uncommon	Rapid swelling in the face, mouth or throat			✓
	Throat tightness			✓
Rare	Severe allergic reaction			Seek emergency help immediately

Refer to the Consumer Information leaflet provided with ITULATEK® for more complete information on side effects and what to do about them. This is not a complete list of side effects. For any unexpected side effects while taking ITULATEK®, contact your doctor or pharmacist.

TIPS TO HELP MANAGE BIRCH ALLERGIES.

Below is a list of ways to help you manage birch allergies.

Check off the ones you are doing now. Circle those that you might want to remember:

- ☐ Keep your house and car windows closed during pollen season
- ☐ Stay indoors on windy days and when the pollen count is high
- ☐ Do what you need to do outdoors on rainy, cloudy or windless days, when there may be less pollen in the air
- ☐ Do not rake leaves or do any outdoor activities that may stir up pollen into the air
- ☐ Keep pets from roaming free, as they can be carriers of pollen
- ☐ Minimize early morning outdoor activities when pollen is commonly released (between 5:00 AM and 10:00 AM)

This material is intended to be used by patients
who have been prescribed ITULATEK®



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