

PART III: CONSUMER INFORMATION

(Standardized Allergen Extract, Short Ragweed (*Ambrosia artemisiifolia*) Sublingual tablet, 12 Amb a 1-U)

This leaflet is part III of a three-part “Product Monograph” published when RAGWITEK® was authorised for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RAGWITEK®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATIONWhat the medication is used for:

RAGWITEK® (RAG-wih-tek) is used for the treatment of adults and children 5 to 65 years of age with a history of allergy to ragweed pollen. Ragweed pollen allergy is characterized by rhinitis (sneezing, runny or itchy nose, stuffed up nose) with or without conjunctivitis (itchy, burning, red or watery eyes).

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

RAGWITEK® has not been tested in patients younger than 5 years of age.

What it does:

RAGWITEK® is a tablet that treats your allergy caused by ragweed. It contains an allergen extract that helps to make you less sensitive to the ragweed pollens you are allergic to.

When it should not be used:

Do not take RAGWITEK® if you:

- have severe or difficult to control asthma;
- have ever had a serious allergic reaction to ragweed allergy shots, tablets or drops;
- are taking beta-blockers (a medicine for heart conditions, such as high blood pressure);
- have any swelling or sores in your mouth;
- are allergic (hypersensitive) to any of the other ingredients of RAGWITEK® (see What the non-medicinal ingredients are).

What the medicinal ingredient is:

The active substance is Standardized allergen extract, Short Ragweed (*Ambrosia artemisiifolia*).

What the non-medicinal ingredients are:

Fish gelatin, mannitol, sodium hydroxide.

What dosage form it comes in:

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

Each tablet contains 12 Amb a 1-U of Standardized Allergen Extract, Short Ragweed (*Ambrosia artemisiifolia*).

WARNINGS AND PRECAUTIONS**SERIOUS WARNINGS AND PRECAUTIONS**

- RAGWITEK® is to be given only by doctors experienced in treating allergies.
- It is very common (in 35% (one-third) of patients) for patients to have mild local allergic reactions with RAGWITEK® (for example: mouth swelling, throat itching or burning, itching in the mouth or ears).
- The first tablet of RAGWITEK® must be taken at the doctor’s office. Your doctor will also tell you to stay for at least 30 minutes to check you for possible allergic reactions.

Serious allergic reactions that require immediate medical attention have happened in patients treated with RAGWITEK®. They are most common early in treatment, but can happen even if patients have been taking RAGWITEK® for months. If you experience serious allergic reactions such as:

- swelling in the throat
- trouble swallowing
- wheezing or trouble breathing
- changes in your voice
- hives
- feeling faint or anxious
- nausea, vomiting, diarrhea or stomach cramps, contact your doctor immediately and get emergency treatment. Stop treatment until your doctor tells you to start taking it again

Once you start taking RAGWITEK® at home, your doctor may prescribe some medications to have with you in case of emergency.

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

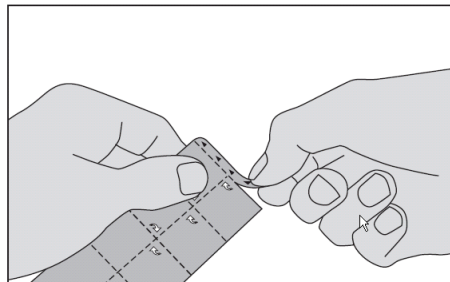
- dizziness, fainting, fast or weak heartbeat, feeling nervous or feeling of “impending doom”
- throat tightness or swelling of the tongue or throat that causes trouble speaking, breathing or swallowing
- wheezing, shortness of breath, cough, chest tightness or trouble breathing
- stomach cramps, vomiting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

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

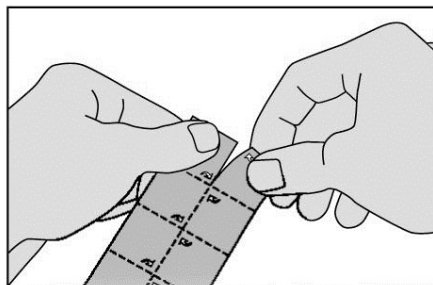
- heartburn, difficulty swallowing, pain with swallowing, or chest pain

Before you take RAGWITEK[®], tell your doctor if you:

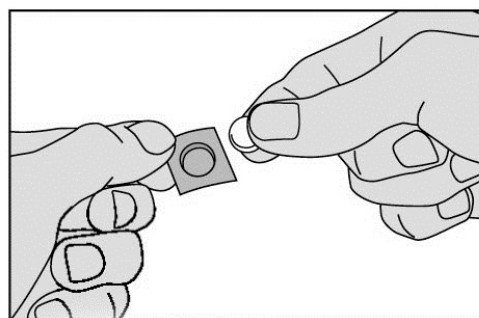
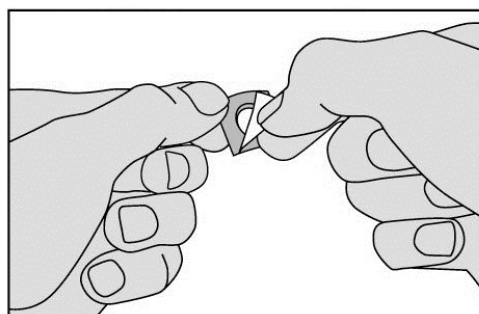
- have ever had a serious allergic reaction to allergy shots, tablets or drops
- have worsening asthma symptoms or breathing problems
- have recently had any mouth injury or mouth surgery (such as a tooth removal)
- are pregnant or could become pregnant
- are breastfeeding or plan to breastfeed. It is not known if RAGWITEK[®] will pass into breast milk
- have diseases which affect the immune system, such as autoimmune diseases, including Multiple Sclerosis (MS), lupus or Rheumatoid Arthritis, or immune deficiency such as HIV/AIDS, or if you had your spleen removed
- have cancer



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.

INTERACTIONS WITH THIS MEDICATION

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 medications while you are using RAGWITEK[®]. **No drug interaction studies have been done in patients taking RAGWITEK[®].**

PROPER USE OF THIS MEDICATION

The first dose of RAGWITEK[®] 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 RAGWITEK[®] at home.

Usual dose:

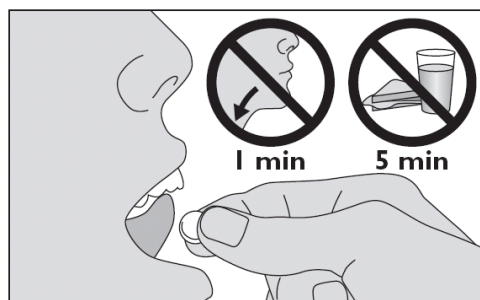
You should start taking RAGWITEK[®] at least 12 weeks before the ragweed pollen season usually begins. Take RAGWITEK[®] exactly as your doctor tells you to take it, usually until the end of the ragweed pollen season.

How should I take RAGWITEK[®]?

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 dissolve in seconds.
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.



General information about the safe and effective use of RAGWITEK®

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 the possible allergic reactions from RAGWITEK® treatment.

Missed Dose:

- If you miss a dose, do not take a double dose to make up for the forgotten dose.
- Increased doses can cause severe allergic reactions.

Overdose:

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

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, RAGWITEK® can cause side effects, including **serious side effects**. The side effects usually happen early in treatment, but can happen even if you have been taking RAGWITEK® for months.

The most common side effects of RAGWITEK® include:

- throat irritation
- itching of the mouth ears or eyes
- swelling or numbness of the mouth

Severe allergic reactions to RAGWITEK® occurred in 2% of patients in clinical trials. Symptoms include:

- swelling of the throat, mouth or tongue
- difficulty swallowing or breathing
- asthma attack/wheezing
- hives/itchy rash
- voice changes (hoarse voice or trouble speaking)

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

Side effects reported by adult patients who were treated with RAGWITEK® in clinical studies include:

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

- **Mouth:** tingling and/ or itching
- **Throat:** irritation in the throat
- **Ear:** itching in the ear

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

- Mouth:** numbness and/or inflammation, swelling at the roof of the mouth
- Tongue:** itching, swelling, inflammation
- Lips:** itching, swelling
- Throat:** difficulty swallowing, pain and/or swelling and/or redness
- Nose:** sneezing, runny nose
- Eyes:** itching
- Other:**
 - headache
 - chest discomfort
 - cough
 - nausea
 - itching

Uncommon [in less than 1% of patients (less than 1 in 100)]:

- Mouth:** mouth discomfort and/or redness and/or burning and/or dryness, inflammation of the mouth, oral discomfort
- Tongue:** pain, tongue disorder
- Lips:** inflammation
- Throat:** tightness, dryness
- Nose:** congestion, uncomfortable feeling
- Eyes:** watery
- Other:**
 - shortness of breath
 - upset stomach
 - itch
 - rash
 - hives
 - change in voice
 - asthma

The side effects observed in children were similar to those in adults. The following side effects were reported in addition or more often in children compared to adults:

- Mouth:** burning (very common), pain (very common), ulcers (common), inflammation of the mouth (common), uvula swelling (common)
- Tongue:** swelling (very common), ulcers (common)
- Lips:** swelling (very common)
- Throat:** irritation (very common), swelling (very common)
- Other:** nausea (very common), change in taste (common), diarrhea (common), vomiting (common), stomach ache (very common)

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

| Symptom/effect | | Talk with your doctor or pharmacist | | Stop taking drug and call your doctor |
|----------------|-------------------------------------|-------------------------------------|--------------|---------------------------------------|
| | | Only if severe | In all cases | |
| Common | Swelling in the mouth | √ | | |
| | Swollen tongue | √ | | |
| | Swelling in the throat | √ | | |
| | Trouble swallowing | | | √ |
| | Chest discomfort | | | √ |
| | Itching all over your body | √ | | |
| | Throat tightness | | | √ |
| | Hives all over your body | √ | | |
| Rare | Severe allergic reactions or asthma | | | Seek emergency help immediately |
| | Shortness of breath | | | |

This is not a complete list of side effects. For any unexpected effects while taking RAGWITEK® contact your doctor or pharmacist.

HOW TO STORE IT

- Store at room temperature (15 to 30 °C).
- Store in the original package and protect from moisture.
- Keep out of reach of children.

REPORTING SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect
- By calling 1-866-234-2345
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

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.

MORE INFORMATION

If you want more information about RAGWITEK®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website or ALK-Abelló A/S website www.alk.net or by calling ALK-Abelló, Inc. at 1-800-325-7354 (for English) or at 1-800-663-0972 (for French)

To report an adverse event related to RAGWITEK®, please contact 1-800-325-7354 (for English) or at 1-800-663-0972 (for French).

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

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