

GRAZAX[®]

(gra-zaks)

Standardised allergen extract of Timothy grass pollen (*Phleum pratense*)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about GRAZAX[®]. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking GRAZAX[®] against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What GRAZAX[®] is used for

GRAZAX[®] contains an allergen extract of grass pollen. It comes in a tablet form which is intended to be absorbed by the body by placing it under the tongue.

GRAZAX[®] is used to treat grass pollen allergies that are characterised by rhinitis (sneezing, runny or itchy nose, nasal congestion) and

allergic conjunctivitis (itchy eyes) in adults and children 5 years or older.

GRAZAX[®] works by increasing your immunological tolerance to grass pollen, thereby reducing the severity of your allergic reactions over time.

Before starting treatment, the doctor will check if GRAZAX[®] is suitable for you by performing the appropriate blood and/or skin prick tests.

GRAZAX[®] is only available with a doctor's prescription.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take GRAZAX[®]

When you must not take it

Do not take GRAZAX[®] if:

- you have an allergy to any of the Other

ingredients' listed at the end of this leaflet

- you have an illness which affects your immune system or have cancer
- you have severe asthma (as assessed by your doctor).
- you have recently had a tooth taken out, had other forms of mouth surgery, or have ulcers or infections in the mouth (refer to **Before you start to take it**).

Do not take the medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you:

- have an allergy to any of the Other ingredients' listed at the end of this leaflet
- are being treated for depression or Parkinson's disease
- have previously been treated for grass pollen allergies and had a severe allergic reaction
- have asthma and a chest infection. Your

doctor may recommend delaying the start of your treatment until you are better

- have recently had a tooth taken out, had other forms of mouth surgery, are planning to have any form of mouth surgery, or have ulcers or infections in the mouth. Your doctor may delay or stop your treatment until your condition has resolved
- are recovering or are in remission from an illness which affects your immune system
- have an inflamed oesophagus
- are pregnant or intend to become pregnant during treatment.
- are breast-feeding or intend to breast-feed during treatment

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and GRAZAX[®] may interfere with each other.

Ask your doctor for more information on medicines to be careful of or avoid while taking GRAZAX[®]

How to take GRAZAX[®]

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to take

The recommended dose of GRAZAX[®] is one tablet per day. Each tablet contains 75,000 SQ-T standardised allergen extract of grass pollen from Timothy grass (*Phleum pratense*).

Always follow the instructions given to you by your doctor or pharmacist.

How to take it

Make sure your hands are clean and dry before handling the medicine. Follow the instructions below when taking GRAZAX[®]:

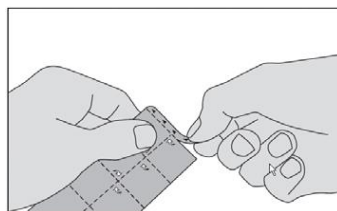


Figure 1: Tear off the strip marked with triangles at the top of the pack.

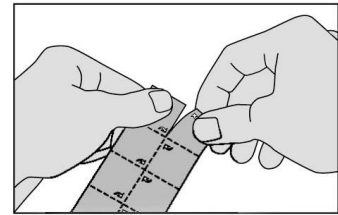


Figure 2: Tear a square off the pack along the perforated lines.

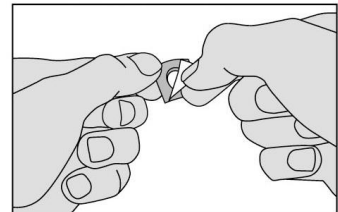


Figure 3: To remove the tablet, fold back the marked corner of the foil and then pull it off. Do not force the tablet through the foil. Doing this may damage it because it breaks easily.

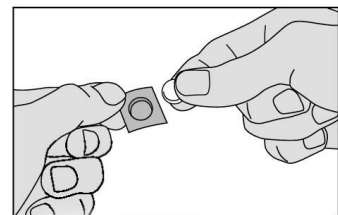


Figure 4: Remove the tablet carefully from the foil and use it immediately.



Figure 5: Place the tablet under the tongue. Allow it to remain there until it has dissolved. Do not swallow for 1 minute. Do not eat or drink for at least 5 minutes.

Your doctor should give you the first tablet under medical supervision and then monitor you for 30 minutes. This gives you the opportunity to discuss any possible side effects with your doctor (refer to **Side effects**).

When to take it

Take the medicine as prescribed by your doctor.

Take your medicine at about the same time each day.

It will also help you to remember when to take it.

Do not consume food or drink for 5 minutes after taking this medicine.

Food can interfere with the absorption of this medicine.

How long to take it

Continue taking the medicine for as long as your doctor tells you to.

Do not stop taking the medicine until your doctor tells you – even if you feel better.

If you forget to take it

If you forget to take a dose, take it later in the day.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 1126) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much GRAZAX[®]. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using GRAZAX[®]

Things you must do

If you are about to be started on any new medicine, inform your doctor or pharmacist that you are taking GRAZAX[®].

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

You can expect some mild to moderate localised allergic reactions during your treatment. In most cases these reactions are only temporary. However if you think these are severe, talk to your doctor to see if you need any anti-allergic medicines such as antihistamines (refer to **Side effects**).

Tell your doctor if you feel the treatment is not helping your condition.

Things you must not do

Do not use GRAZAX[®] to treat any other conditions unless your doctor tells you to.

Do not give this medicine to anyone else even if they have the same conditions as you.

Do not give this medicine to children under 5 years of age.

Do not stop taking your medicine without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Side effects

Tell your doctor or pharmacist if you have any unpleasant effects while taking GRAZAX[®] even if you do not think the effect is connected with this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need to seek medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Itching of the mouth or tongue
- Irritation of the throat
- Development of a cold
- Itching of the ear
- Headache
- Prickling sensation or numbness of the mouth or tongue
- Itching of the eyes
- Swelling of the lips
- Itching or painful sensation of the tongue
- Inflammation, discomfort or burning sensation in the mouth or tongue
- Stomach pain or discomfort
- Diarrhoea
- Feeling sick (nausea)
- Indigestion
- Blistering of the mouth or tongue
- Mouth or tongue ulcers
- Vomiting
- Fever
- Itching of the nose
- Dizziness or wheezing.

Tell your doctor as soon as possible if you notice any of the following:

- Pain when swallowing
- coughing
- heartburn
- Hoarseness
- Tightness in the throat

- Sensation of something stuck in the throat

In most cases these reactions are only temporary.

If any of the following happen, stop taking GRAZAX[®] and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Worsening of existing asthma
- Rapid swelling of face, mouth or throat
- Difficulties in swallowing or breathing
- Voice changing
- Hives
- Severe discomfort.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using GRAZAX[®]

Storage

Store the blister pack in the carton to protect the tablets from light.

Keep it in a cool dry place where the temperature stays below 25°C.

Do not store GRAZAX[®], or any other medicine, in the bathroom or near a sink. Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any GRAZAX[®] that is left over.

Product description

What GRAZAX[®] looks like

GRAZAX[®] tablets are white to off-white with an imprint on one side. The tablets are individually packed in blister foils.

The following pack sizes are available: 10, 30, 90 or 100 tablets.

Not all pack sizes may be marketed.

Ingredients

Active ingredients

Each GRAZAX[®] tablet contains 75,000 SQ-T standardised allergen extract of grass pollen from Timothy grass (*Phleum pratense*) as the active ingredient.

Other ingredients

The tablet also contains:

- gelatine (from fish)
- mannitol
- sodium hydroxide.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Distributor

GRAZAX[®] is distributed in Australia by:

Seqirus (Australia) Pty Ltd
ABN: 66 120 398 067
63 Poplar Rd
Parkville 3052
Victoria

Australian Registration Number

AUST R 267955

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