

In order to gain maximum benefit from treatment with GRAZAX[®], it is important that a tablet is taken, as prescribed by the doctor, every single day. Should you forget to take a tablet, take it later in the day if possible, but otherwise just continue with your normal once-daily routine. Do not take a double dose to make up for a forgotten tablet.

It is important that the first GRAZAX[®] tablet be taken under medical supervision. This is to ensure that the tablet is taken correctly and to provide you with the opportunity to discuss any side effects with the doctor or nurse.

If you experience side effects that are worsening on a daily basis, please contact your doctor or nurse and discuss if treatment of the side effects with antihistamines should be considered (such as with nasal sprays). In rare cases the local side effect may persist despite adding these medications and/or be severe enough that requires the doctor to consider stopping therapy.



Taking GRAZAX[®] every day is important

In order to decrease your hay fever symptoms and to maintain the control of symptoms once the treatment is stopped, the body needs to build up a tolerance to the grass pollen to which you are allergic. Therefore, it is important that you remember to take GRAZAX[®], as prescribed by your doctor or nurse, both when you have symptoms as well as when you are not bothered by symptoms.

Possible side effects

The most common side effect of GRAZAX[®] treatment is itching of the mouth (a tingling sensation most often experienced under the tongue). This is a temporary effect that starts after taking a tablet, and normally lasts for a period of minutes to hours. However, after approximately one week of treatment, the majority of patients no longer experience itching of the mouth.

Other possible side effects with GRAZAX[®] treatment include itching of the ears, sneezing, throat irritation, swelling of the mouth (most often the area under the tongue), abdominal pain, vomiting, and localised swelling of the lip. As with itching of the mouth, these side effects mainly occur within the first week of treatment, are mild-to-moderate in severity, and are short-lived.

In the unlikely event that you experience a more severe side effect with GRAZAX[®] treatment, such as difficulty swallowing, difficulty breathing, rash, a change in voice, dizziness, or a feeling of fullness in the throat, then you should contact a doctor immediately. If you have asthma and the symptoms worsen while taking GRAZAX[®], you should also consult a doctor. In both these cases, you should stop taking GRAZAX[®] until advised otherwise by the doctor.

Reporting of side effects

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme. By reporting side effects you can help provide information on the safety of this medicine. UK: www.mhra.gov.uk/yellowcard Republic of Ireland: www.hpra.ie



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A patient's guide to GRAZAX[®]



What is GRAZAX®?

GRAZAX® is an allergy immunotherapy tablet.

It is suitable for adults and children of 5 years of age and older. It contains a grass pollen extract, which helps you to build up a natural tolerance to grass pollen. In this way, GRAZAX® is able to target the underlying cause of your hay fever, and not just the symptoms.



Before you take GRAZAX®

GRAZAX® will be prescribed to you by a doctor or nurse with experience in the treatment of allergy. Before starting GRAZAX® treatment it is very important that you read the patient information leaflet inside the GRAZAX® packaging.

You should not take GRAZAX® if:

- You are allergic (hypersensitive) to any of the excipients in the GRAZAX® tablet (other than the grass pollen extract).
- You have an illness which affects the immune system.
- You have severe asthma as assessed by your doctor (GRAZAX® can be used if you have mild or moderate asthma).
- You have cancer.
- You have a severe inflammation in the mouth.

Take special care with GRAZAX® if:

- You have recently had a tooth taken out (or other forms of oral surgery). In this case treatment with GRAZAX® should be stopped for 7 days to allow the oral cavity to heal.
- You have a severe allergy to fish.
- You have previously had injection grass pollen allergy immunotherapy and experienced severe allergic reactions, since there may be an increased risk of experiencing a similar reaction with GRAZAX®.

If you have any of the above (or if you are unsure) it is important that you talk to your doctor or nurse before you start taking GRAZAX®, or while GRAZAX® is being used.

How to take GRAZAX®

GRAZAX® should be taken once-daily.

To get the best effect, you should start taking GRAZAX® at least 2-4 months prior to the expected start of the grass pollen season, and continue treatment all year round. It is recommended to continue daily treatment for 3 years.

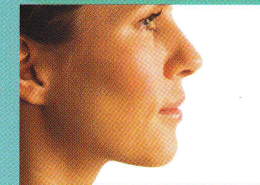
The tablet should be taken out from the blister card with dry fingers, it is important that the tablet is placed **under** the tongue, where it will dissolve within seconds. You should avoid swallowing for 1 minute, and avoid food and drink for 5 minutes after taking the tablet.



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Food and drink should be avoided for 5 minutes after taking the tablet.

