

ITULAZAX® – sublingual allergy vaccination in tablet form

The principle behind allergy vaccination is to supply your body with the substance (allergen) you are allergic to in controlled doses. The cause of the allergy is treated by helping the immune system to build tolerance to that particular allergen.

ITULAZAX® is a sublingual allergy vaccination in tablet form. It contains standardized allergen extract from birch pollen. It treats your allergy to birch and pollen from the birch homologous group alder, hornbeam, hazel, oak and beech. , by slowly increasing your immune system's tolerance to the allergens from birch, hazel, or, alder and oak. This leads to a decrease in symptoms. After having built tolerance to the allergen you will need to take less (or in some cases no) medication to relieve symptoms.

The tablet is indicated for adults 18-65. It is important for you to follow your doctor's prescription carefully to make the treatment as effective as possible. **The treatment period is 3 years.**

Treatment with ITULAZAX®

If you have any questions or are unsure about your treatment, it is important to talk to your doctor before you start taking the tablets. If you suffer from asthma, you should take your asthma medication throughout the treatment period as prescribed by your doctor.

ITULAZAX® is taken once a day

You should start treatment with ITULAZAX® at least 16 weeks before the start of the pollen season to get clinical efficacy. The treatment period is 3 years, one tablet daily. It is recommended that the first tablet is taken under medical supervision and that you stay at the doctor's office for 30 minutes after taking the tablet. This is to check that you are taking the tablet correctly and to enable a discussion and treatment of possible side effects.

Exercise caution when taking ITULAZAX® if:

- You have had a tooth extracted, has lost a tooth or has had any other kind of procedure in your mouth. You must stop treatment for seven days until your mouth has healed.
- You have recently received an allergy vaccination in injection form and experienced severe side effects.
- You have a severe fish allergy. ITULAZAX® contains very small amounts of fish gelatine.
- If you suffer from asthma and the symptoms get worse when taking ITULAZAX®, you must contact your doctor.

You must not take ITULAZAX® if you have:

- Uncontrolled or severe asthma
- Hypersensitivity to any substance in the tablet
- A disease that affects the immune system or cancer
- Inflammatory conditions in the mouth, e.g. sores, blisters or fungal infections

ITULAZAX® and pregnancy:

If you become pregnant during the treatment, contact your doctor, who will decide whether or not it is suitable for you to continue your treatment.

How to take ITULAZAX®

- Remove the tablet from the blister pack using dry fingers.
- Place the tablet under your tongue. Change between the right and left sides.
- The tablet dissolves in a few seconds.
- Do not swallow for a period of 1 minute after taking the tablet.
- Wait 5 minutes before eating or drinking.
- It is a good idea to rinse your mouth after 5 minutes.

If you forget to take a tablet, you can take it later on the same day. Never take a double dose to compensate for forgetting to take a tablet; continue as normal by taking one tablet per day.

- Avoid brushing your teeth before taking the tablet. Wait until afterwards.
- Avoid scratching or touching your eyes if you have just had a tablet in your hand.

Follow the prescription from your doctor

To reduce the allergic symptoms and to make sure the treatment has a lasting effect, your body needs to build up a tolerance to the substance you are allergic to, slowly and over a long period of time. It is important to remember to take one tablet every day, including days when you do not have any symptoms. To get the best results possible from the treatment, it is important to follow the doctor's prescription carefully.

Remember the following when taking ITULAZAX®

- Do not brush your teeth before taking the tablet, but afterwards.
- If you have a dry mouth, rinse your mouth out with water beforehand.
- Wash your hands after taking the tablet.
- Rinse your mouth 5 minutes after taking the tablet.
- You can take the tablet whenever you want during the day.
- Never take two tablets on the same day.
- You can take anti-histamines if you suffer from itching in your mouth when starting the treatment (you should always discuss this with your doctor before taking anti-histamine).
- If you suffer any allergy problems or symptoms, use your allergy medication when necessary.

Possible side effects

Patients taking ITULAZAX should primarily expect mild to moderate local allergic reactions to occur within the first few days of treatment and disappear within a few months (in many cases within a week or two). For the majority of events, the reaction should be expected to start within 10 minutes after intake of ITULAZAX on each day of occurrence and abate within an hour. In rare cases the side effects can persist and be so severe that you have to stop the treatment.

- The most common side effect is itching in the mouth.
- You may also feel a tingling sensation, often under your tongue, immediately after taking the tablet.
- Other more unusual side effects are itching in your ears, sneezing, throat irritation, swelling in the mouth – normally under your tongue, stomach pains, vomiting and localised swelling of the lips.

Contact your doctor if:

- You unexpectedly suffer from more severe side effects, such as breathing or swallowing difficulties, rash, a change in your voice, dizziness or a lump in your throat.
- If you suffer from asthma and your asthma symptoms get worse.

In all of these cases, you should stop taking ITULAZAX® until the doctor makes a decision to the contrary.

Questions and answers

Why is it recommended that the first tablet is taken at the doctor's office?

We recommend taking your first tablet at the doctor's surgery to check that you are taking the tablet correctly. It also gives you the chance to discuss any side effects with your doctor, and allows the doctor to treat them, if necessary.

What are the most common side effects?

The most common side effect of ITULAZAX® is itching in the mouth. This is a temporary side effect that can start from the time you take the tablet and normally goes away by itself after a few minutes or an hour. After a week of treatment, this side effect goes away for most people. Other possible side effects of ITULAZAX® include itching in your ears, sneezing, throat irritation and swelling in your mouth. Just as with the itching in the mouth, these are examples of allergic reactions which normally only last for a very limited period when you start treatment. Your doctor should have given you detailed information about ITULAZAX®, but to be on the safe side, read the patient information leaflet in the pack before starting the treatment

What should I do if my asthma symptoms get worse?

If you suffer from asthma and the symptoms get worse when being treated with ITULAZAX®, you must contact the doctor, who will assess whether your treatment should be stopped. It is important for you to take the asthma medication prescribed by your doctor.

I have previously reacted strongly to an allergy vaccination against birch pollen in injection form. Can I take ITULAZAX®?

If you have previously reacted strongly to an allergy vaccination against birch pollen in injection form, you may be at a higher risk of similar reactions when being treated with ITULAZAX®. If this is the case, your doctor should make a full assessment before you start the treatment.

What should I do if I forget to take a tablet?

If you forget to take a tablet, you can take it later on the same day. Do not take a double dose to compensate for forgetting to take a tablet.

Should I stop taking ITULAZAX® treatment during the pollen season?

No, during the pollen season, you should continue the treatment as normal

Should I continue to take drugs to relieve my symptoms when taking ITULAZAX®?

You should continue to take medication to relieve your symptoms when necessary.

I have asthma. Should I continue to take my asthma medicine?

Yes, you should continue to take the asthma medication prescribed by your doctor.