Patient information on sublingual specific immunotherapy

Dear patient,

Often, specific immunotherapy involving the continuous administration of the allergy trigger can help your body to develop a natural tolerance. If treatment is successful, your body becomes tolerant – and therefore less sensitive – to the allergy trigger over the course of treatment – the cause of the allergy is treated! This type of therapy often also has a positive effect on mucosal (such as your nasal cavity) hypersensitivity and susceptibility to mucosal infections. In the case of sublingual immunotherapy ("under the tongue"), treatment is administered in the form of a tablet or liquid solution. This treatment is recommended when adequate allergen avoidance is not possible and drug therapy has proved unsatisfactory. It does not cause new allergies. Alternatively, the mode of allergen administration can be varied (allergen administration via injection under the skin of the upper arm at regular intervals at a medical practice instead of sublingual allergen administration, often in tablet form), provided a suitable preparation is available and there are no contraindications to this form of administration in your particular case.

In order to ensure the success of your or your child’s treatment, please observe the following points:

1. Treatment success depends on your compliance (daily administration!). Since the treatment is recommended for a period of 3 years, this requires a high level of cooperation from you. We would ask you to participate in treatment only if you are confident that you intend and are able to perform the treatment reliably (fulfilling these criteria increases the chances of benefiting from treatment).

2. Please attend the follow-up appointments arranged for you at your doctor’s practice regularly and obtain follow-up prescriptions in a timely manner. To achieve optimal and long-lasting treatment results (even after treatment is concluded), a full 3 year course is recommended.

3. The first allergen administration should be performed at your doctor’s practice under his/her supervision. This is to ensure that the tablet or drops are taken in the appropriate manner. Sublingual immunotherapy is very well tolerated. Local symptoms, such as itching in the mouth or throat (rarely also swelling of the tissue in this area, but generally only transiently in the initial treatment phase) sometimes occur. Gastrointestinal symptoms are rare. Major allergic reactions are extremely rare and have only been seen to date in patients with uncontrolled asthma. Discuss these possible side effects with your doctor.

4. Inform your doctor promptly if you: need to undergo tooth extraction or if any other form of surgery in the oral cavity is planned; have an infection in the oral cavity; taking new medication; or if you become pregnant. Please also read the carefully the instructions for use in the medication package.

5. It is important for you to attend appointments as scheduled or to inform your doctor sufficiently in advance if you are unable to attend an appointment.
6. Please talk to your doctor about how to proceed in the event of side effects or if you are suffering from other disorders (e.g., flu, asthma aggravation); also, remember your regular follow-up appointments with your doctor, as well as appointments to collect prescriptions.

7. Please pay careful attention to these instructions to ensure that your treatment can be carried out successfully, hopefully, without troublesome side effects! The information provided above is not intended as a substitute to reading the product information leaflet and serves only as additional information. Your doctor can provide you with further important information during the consultation and will ask for your informed consent prior to the start of treatment.

Additional medical notes (e.g., individual risks):

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**Patient consent to sublingual specific immunotherapy**

I have read and understood the information on my allergic disease and on the possible treatment options. My doctor has explained to me the planned sublingual immunotherapy as well as alternatives and, having had a suitable period of time to consider the options, I consent to undergo this form of treatment using the preparations selected. My questions relating to this treatment have been answered. My doctor has informed me of the possibility of side effects and I am aware that it is not possible to predict treatment success with certainty. Should side effects occur, I will contact my doctor. For further information, I can refer to the product information leaflet. In addition, my doctor continues to remain available to me as my person of contact.

I confirm that I have no further questions.

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**DATE**

**SIGNATURE (patient or legal guardian*)**

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**DATE**

**SIGNATURE (doctor)**

*In cases where parents have joint custody but only one parent signs, he/she confirms by signing that the other parent gives their consent, or that they, the signatory, have sole custody.