

Subcutaneous Specific Immunotherapy

Patient Information



Specific Immunotherapy

Allergy tests performed by your doctor showed that you (or your child) suffer from an allergy. Allergic symptoms such as watery and itchy eyes (conjunctivitis), sneezing attacks and runny nose (= rhinitis), laboured breathing (= asthma), skin irritations (eczema), gastrointestinal disorders, migraine or sleep disorders appear when the affected person is exposed to substance(s) (i.e. pollen, mites, animals) to which he/she is hypersensitive. Best would be to avoid these allergens. However, it is often not possible to avoid allergen contact in daily life.

Your doctor has, therefore, recommended you (or your child) a specific immunotherapy (hyposensitization) in the form of a series of injections (shots cure). This means that during scheduled visits increasing allergen doses will be injected beneath the skin (subcutaneous) of the upper arm. The sensitivity of the immune system is thereby reduced gradually.

The treatment course takes three years in general, and it demands your continued cooperation. Keep going – it's worth it, since recent clinical studies demonstrated a more and more increasing therapeutic success in the course of these three years. This means your complaints will increasingly vanish and you will need markedly less anti-symptomatic medications by the time! Studies indicated that long-term efficacy is sustained even after the end of the three treatment years.

Nevertheless, specific immunotherapy (SIT) must not be administered when certain disorders are present or certain medications are used. Before SIT is initiated, you should discuss your medical history with your doctor.

The following considerations are of utmost importance for the success of this treatment:

- Strictly comply with the visits scheduled by your doctor because otherwise, regular up-titration of allergen doses is not feasible and this would jeopardize the therapeutic success. Usually, there will be one-week intervals between the visits in the beginning, in the later course larger intervals (up to 4-8 weeks) may be sufficient.
- After each injection you will have to stay in the doctor's office for at least 30 minutes as the doctor will monitor how you tolerate the injection. The administered allergen may induce symptoms such as itchy eyes, nose or breathing disorders as well as skin rash, laboured breathing, cough, feeling of indisposition or dizziness. In exceptional cases a life-threatening circulatory collapse may develop rather quickly. Typical alarm symptoms are itching, burning and heat sensation on and under the tongue and in the throat and particularly marked on the palms of the hands and the soles of the feet. Inform the medical staff im-

mediately when you experience possible signs of side effects because serious consequences can be avoided when timely countermeasures are taken.

After the injection, redness, itching and/or swelling may develop at the injection site. These and other side effects may appear also as long as several hours after the injection.

- Please tell your doctor before the next injection how you (or your child) tolerated the injection administered before. Furthermore, inform him/her before each injection on the following aspects:
 - changes of all drug treatments (also over-the-counter medicines)
 - new complaints (including cold-like symptoms)
 - impending vaccinations
 - existing pregnancy
 - planned longer absence
 - changes of living conditions (such as moving home, new occupation)
- Please also observe on the treatment day:
 - sometimes you may experience a feeling of tiredness. You must keep this in mind when you are driving a car, operating machinery or working without firm support.
 - after the injection you should avoid hot showers, sauna visits, strenuous physical activities, and alcohol consumption.

So far, specific immunotherapy is the only therapeutic approach that targets the root cause of allergy. Clinical studies clearly demonstrated the efficacy of this treatment: the clinical symptoms subsided and the use of symptomatic medications was reduced. This therapeutic success may sustain after the end of treatment. Thus, in the long run you may experience less physical discomfort, need less medication, have a markedly reduced asthma risk as well as a reduced risk of sensitization by other allergens.

Your doctor will discuss with you any further questions.





Statement

For the doctor's records

Informed consent discussion notes:

Alternatives to SIT not sufficient

- Allergen avoidance
- Pharmacologic treatment

Chances of success

- As regards the allergen
- As regards the duration of the allergic disease
- As regards the patient's age

Side effects (a.o.)

- Asthma
- Anaphylactic shock

Instructions for the patient

- Regular visits
- 30minutes-stay at the office after the injection
- Unsolicited report of complaints
- Reporting of late reactions, pregnancy, change of medication

Informed Consent

(Doctor's Office/Clinic Stamp)

today discussed with me all questions regarding specific immunotherapy of interest to me. I have been given instructions on what to do/not to do during and after treatment, and I have understood these instructions. I agree that additional and concomitant procedures may become necessary.

I also agree that my name, address, date of birth, and health insurance data may be shared with the manufacturer when ordering my treatment via my pharmacy, and that my name and date of birth may be captured, processed, and held on a computer by the manufacturer for the duration of treatment to ensure drug safety with regard to allergen composition. This information will not be shared with third parties.

I consent to undergo specific immunotherapy as recommended by my doctor.

Place/Date

Signature of Patient or Parent(s)/Guardian

Place/Date

Signature of Physician

Statement

For the patient's records

Informed consent discussion notes:

Alternatives to SIT not sufficient

- Allergen avoidance
- Pharmacologic treatment

Chances of success

- As regards the allergen
- As regards the duration of the allergic disease
- As regards the patient's age

Side effects (a.o.)

- Asthma
- Anaphylactic shock

Instructions for the patient

- Regular visits
- 30minutes-stay at the office after the injection
- Unsolicited report of complaints
- Reporting of late reactions, pregnancy, change of medication

Informed Consent

(Doctor's Office/Clinic Stamp)

today discussed with me all questions regarding specific immunotherapy of interest to me. I have been given instructions on what to do/not to do during and after treatment, and I have understood these instructions. I agree that additional and concomitant procedures may become necessary.

I also agree that my name, address, date of birth, and health insurance data may be shared with the manufacturer when ordering my treatment via my pharmacy, and that my name and date of birth may be captured, processed, and held on a computer by the manufacturer for the duration of treatment to ensure drug safety with regard to allergen composition. This information will not be shared with third parties.

I consent to undergo specific immunotherapy as recommended by my doctor.

Place/Date

Signature of Patient or Parent(s)/Guardian

Place/Date

Signature of Physician

Allergopharma Joachim Ganzer KG | 21462 Reinbek near Hamburg
Phone +49 40 72765-0 | Fax +49 40 7227713 | info@allergopharma.de | www.allergopharma.com