NOVO-HELISEN® Depot

Breathe better, live better[1,2]

NOVO-HELISEN® Depot is a house dust mite depot preparation approved for patients from the age of 5, as well as an individual product solution for the subcutaneous allergen immunotherapy (SCIT) of rare allergies such as animal epithelia or mold allergy.[4] Due to the adsorption to aluminum hydroxide, the allergen release at the injection site is delayed, which minimizes side effects ("depot effect").

Efficacious
in allergic rhinitis and asthma in children* and adults[1-3,**]

Asthma-preventive
2 years after allergen immunotherapy[5,**,#]

Well-tolerated
in clinical* and everyday practice[**,1-3,6]

Available allergen sources

NOVO-HELISEN® Depot		
House dust mites		
708	Dermatophagoides farinae	50 %
725	Dermatophagoides pteronyssinus	50 %
Mold		
400	Alternaria alternata (A. tenuis)	100 %

NOVO-HELISEN® Depot		
Epithelia		
306	Dog epithelia	100 %
309	Cat epithelia	100 %
314	Horse epithelia	100 %

* Proven for Alternaria alternata (A. tenuis) and house dust mites.
** Proven for house dust mites.
# Confirmed in a retrospective study in an open controlled design.

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ALLERGEN IMMUNOTHERAPY

NOVO-HELISEN® Depot

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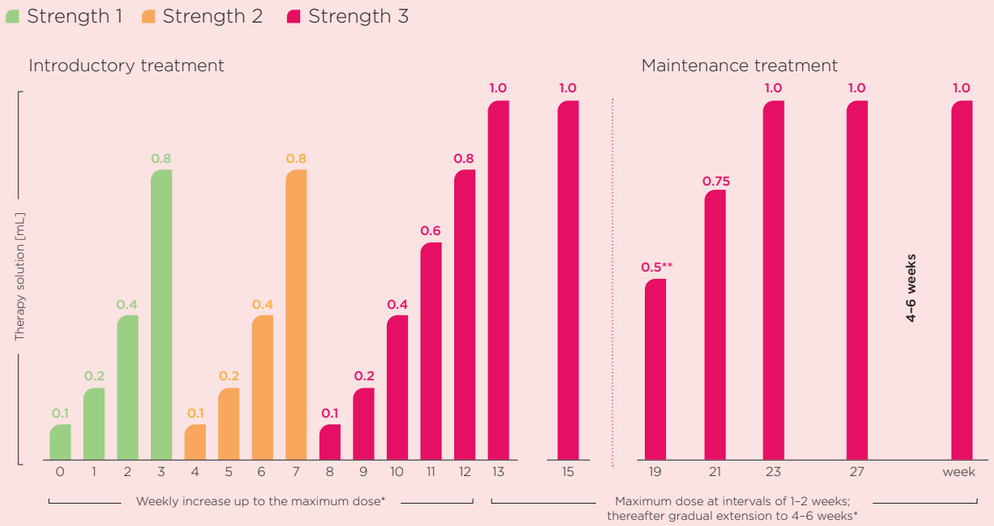
NOVO-HELISEN® Depot

Dosage recommendations[4]



Dose modification in case of interval exceedance[4]

Introductory treatment

Interval since the last injection	Dosage modification
> 2 weeks	Dose reduction by one level
> 4 weeks	New start

Maintenance treatment

Interval since the last injection	Dosage modification
> 6 weeks to 8 weeks	Dose reduction by 50 % then continue according to the respective dose escalation scheme
> 8 weeks	5 % of the last tolerated dose
> 52 weeks	New start

Introductory treatment

Strengths 1, 2, 3

Maintenance treatment

1x Strength 3

2x Strength 3

* The dosage is determined on the basis of the patient's tolerance.

** Allergen-dependent differences in down-dosing after batch change: Dust mite down-dosing to 50% of last dose. Increase with an intermediate step at intervals of 1–2 weeks to full dose, for example 0.5; 0.75; 1.0 mL. Alternaria alternata (A. tenuis) and animal epithelia down-dose to 20 % of the last dose. Increase with intermediate steps at intervals of 1–2 weeks to full dose, for example 0.2; 0.4; 0.6; 0.8; 1.0 mL.

For further information, please see summary of product characteristics or basic information (page 3)

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NOVO-HELISEN® Depot

Note

This information about Allergopharma products, dosage recommendations and the availability of allergen sources may vary from country to country. For specific information, please contact your local distributor.

NOVO-HELISEN® DEPOT

Composition: Standardized allergen extracts from mites, epithelia or molds for allergen immunotherapy, adsorbed to aluminum hydroxide, preserved with phenol and suspended in physiological saline with sodium hydrogen carbonate; water for injection. The proportions of the various allergens used are specified on the pack. Novo-Helisen® Depot is characterized by physico-chemical and immunological analyses including the quantification of selected major allergens.

Indications: Causal treatment of allergic (IgE-mediated) diseases triggered by exposure to storage mites, animal epithelia, molds and house dust mite allergens, e.g., for patients diagnosed with allergic rhinoconjunctivitis and/or allergic bronchial asthma. Novo-Helisen® Depot individual formulations are used to treat adults, adolescents and children aged from the age of 5.

Contraindications: Hypersensitivity to any of the excipients, uncontrolled asthma, irreversible changes in the reaction organ, inflammatory/febrile diseases, severe acute or chronic diseases (e.g., malignant diseases, active tuberculosis), clinically significant cardiovascular insufficiency (due an increased risk of adverse reactions to adrenaline), treatment with beta-blockers (local, systemic), diseases of the immune system (autoimmune diseases, immune complex-induced immunopathies, immunodeficiencies, multiple sclerosis etc.), severe mental disorders.

Side effects: Local and/or systemic reactions (up to anaphylactic shock) must be expected, then stop injection immediately. Anaphylactic reaction; anaphylactic shock; conjunctivitis (allergic); rhinitis (allergic); sinusitis; asthma; stridor; bronchial obstruction; cough; dyspnoea; rhonchi; tachycardia; chest discomfort; cyanosis; flushing; hypertension; blood pressure decreased; circulatory collapse; cold sweat; chills; feeling cold; body temperature increased; pyrexia; malaise; asthenia; sensation of foreign body; anxiety; dizziness; headache; altered state of consciousness; loss of consciousness; dysphagia; dry mouth; stomatitis; vomiting; gastroenteritis; pain; neck pain; bone pain; arthralgia; lipoatrophy; angiooedema; swelling face; swelling; urticaria; skin reaction; pruritus (generalized); rash generalized; eczema; erythema; granuloma; at the injection site: reaction, swelling, pruritus, erythema, urticaria, warmth, oedema, vesicles.

For additional information on doses, administration etc., see package insert. The general classification for supply depends on local requirements.

Date of information: September 2020

References

1. Yukselen A, Güneser Kendirli S, Yilmaz M, Ufuk Altintas D, Bingol Karakoc G. Effect of One-Year Subcutaneous and Sublingual Immunotherapy on Clinical and Laboratory Parameters in Children with Rhinitis and Asthma: A Randomized, Placebo-Controlled, Double-Blind, Double-Dummy Study. Int Arch Allergy Immunol 2012; 157: 288–298.
2. Kuna P, Kaczmarek J, Kupczyk M. Efficacy and safety of immunotherapy for allergies to Alternaria alternata in children. J Allergy Clin Immunol 2011; 127: 502–8.
3. Grewe M, Kettner J, Doemer C, Meyer H, Cromwell O, Narkus A. Efficacy and safety of specific immunotherapy with house dust mites allergen extract. Abstract Book EAACI 2006:227.
4. SUMMARY OF PRODUCT CHARACTERISTICS: NOVO-HELISEN® DEPOT Individual Formulations Version-3a-INT from 09/2020.
5. Peng H, Wei Li C, Bin Lin Z, Ying Li T. Long-term Efficacy of Specific Immunotherapy on House Dust Mite-Induced Allergic Rhinitis in China. Otolaryngology– Head and Neck Surgery 2013; 149: 40–46.
6. Ullrich D, Thum-Oltmer S, Mussler S, Jaeschke B. Successful specific subcutaneous immunotherapy (SCIT) with non-modified semidepot pollen and mite preparations. Results of a post-marketing surveillance study. Allergo J 2007; 16: 193–8.

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