This information is valid for the Slovak Republic and may differ for other countries. For detailed information, please contact the relevant foreign representative:

http://www.imuna.sk/en/o-nas/zahranicne-zastupenia-a-business-development/

Abridged Product Information

Product name: H-Al per os. **Composition:** 1 mL of the product contains allergen extracts: pollen allergens 1 PNU – 10,000 PNU, 1 JSK - 10,000 JSK, allergens from dust and animal epithelia 0.1 PNU – 10,000 PNU, bacteria allergens 0.1 PNU – 10,000 PNU, allergens from fungi and yeasts 0.1 PNU – 10,000 PNU, mite allergens 1 PNU – 10,000 PNU, insect allergens 0.5 PNU – 5,000 PNU. **Dosage form:** Peroral drops. **Therapeutic indications:** Allergen immunotherapy (AIT) is recommended as an appropriate method of immunotherapy in children and adults with a confirmed allergic reaction mediated by antidotes of the IgE type. Allergen immunotherapy is performed in case of confirmed hypersensitivity to allergens which cannot be eliminated from the environment, are present in a significant amount, and cause troubles substantiating the disease. Allergens which cause troubles identical to the positive result of the test with diagnostic allergens are selected. If a patient suffers from hypersensitivity to several allergens, the allergen immunotherapy should be performed using corresponding allergens separately or alternately. The allergen immunotherapy with pollen allergen preparations can be performed out of the pollen production period and during the season the therapy should be discontinued, or blocking doses can be administered; recently, however, the all-year therapy is mostly applied. **Dosage and administration:** Application of an allergen preparation at the AIT commencement is carried out in two stages. In the initiation stage, the maximum tolerated dose is reached by gradual increases in doses and concentrations. In the maintenance stage, the maximum tolerated dose is repeatedly administered.
The therapeutic allergen preparation is administered once daily (in the morning or in the evening), 30 minutes before a meal. Prior to the application, a patient should remove a plastic cover from the dosing set body and replace it with the upper part of the pump which is supplied separately in a sterile package and is included in the product packaging. Respective number of drops are dropped from the bottle containing the allergen preparation on a tea spoon. A mixture of flavoured water can be added to the allergen. *1. Conventional AIT*. The procedure is specified in the recommended guide scheme which should be adjusted depending on a patient's tolerability and health condition. Lower concentrations of allergens are usually administered three times a week. With higher concentrations, intervals between individual doses are extended and they are administered twice or once a week. *2. Alternative AIT scheme.* AIT is commenced with the lowest concentration. It is gradually increased up to the highest concentration. **Contraindications:** Systemic diseases affecting the immunity system (collagenoses, diseases from autoimmunity, serious immunodeficiency), malign diseases, serious chronic diseases, in person with mental disorders, whose cooperation cannot be expected, central spastic diseases, serious infections and inflammatory processes in organs affected with allergic symptoms, active tuberculosis, severe form of atopic eczema, simultaneously performed immunosuppression, therapy with β-blockers, repeated allergic reactions during properly performed allergen immunotherapy. **Special warnings:** Individual approach is required when allergens are applied to children below 3 years of age, in cortico-dependent allergy, in acute infections and in acute progression of a primary allergic disease. AIT must be discontinued 14 days prior to a planned preventive vaccination, AIT is then restored 1 week after the tuberculin tests, 2 weeks after the application of inactivated vaccines, 4 weeks after the application of live vaccines, 8 - 12 weeks after the application of BCG vaccine. **Drug and other interactions:** AIT must be discontinued 14 days prior to a planned preventive vaccination, AIT is then restored after the interval determined by a vaccine type. **Application in pregnancy and during lactation:** The therapy must not be commenced during pregnancy. If pregnancy commences during the AIT, a physician should thoroughly evaluate the risk

for a mother and a child when considering potential continuation with the therapy. During breastfeeding, AIT is carried out upon the attending physician-allergologist's decision. **Effect on ability to drive and operate machines:** The product was not proved to affect attention during driving or operating machines. **Adverse effects:** If the allergen immunotherapy is indicated and applied by an experienced professional, the risk of adverse reaction is relatively low. Allergic reactions include provocation of symptoms, e.g. – watery cold, sneezing, tearing and burning eyes, cough, shortness of breath, and deterioration of skin symptoms. Non-allergic reactions include overall fatigue, nausea, sleepiness, and increased body temperature. **Packaging:** Bottles filled up to 9 mL. Not all types of allergens are necessarily available on the market. **Holder of marketing authorisation:** SEVAPHARMA a.s., Průmyslová 1472/11, 102 19 Prague 10, the Czech Republic. **Availability:** Product is subject to medical prescription. **Prior to prescription, please study the Summary of Product Characteristics. Last text revision date:** December 2012**.**