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: D-AL PRICK TEST. **Composition:** 1 mL of the product contains allergen extracts: pollen allergens - 1,000 PNU, 10,000 PNU, 1,000 JSK, 10,000 JSK, mite allergens - 1,000 PNU, 10,000 PNU, allergens from moulds and yeasts - 1,000 PNU, 10,000 PNU, insect allergens - 500 PNU, 5,000 PNU, allergens from dust and animal epithelia - 1,000 PNU, 10,000 PNU or dilution ratio 1:1. **Indications:** D-AL PRICK TEST is only intended for the diagnostics purposes, to confirm a patient's specific hypersensitivity (type I) to a particular allergen, or to determine the hypersensitivity degree. **Dosage and administration:** The test is usually performed on the volar forearm. Tested allergens are applied, in a respective concentration, to the skin as drops with the minimum spacing of 2 cm. A sterile disposable lancet is used to make a gentle skin puncture vertically through an allergen drop, so that the puncture site does not bleed. The allergen drop is gently dried after about 60 seconds. The reaction is evaluated after 15 - 20 minutes. Reaction assessment is based on the boil size. The boil diameter and size is determined by the maximum diameter (D 1) and the diameter in the perpendicular direction towards the maximum diameter (D 2). The average size D = (D 1 + D 2) : 2. Diameter measurements are made using a gauge. A reaction is assessed as positive, if the average boil size D is 3 mm or more. The skin test with a relevant allergen is always carried out concurrently with the negative and positive control to assess non-specific skin reactivity and potential impact of medications (e.g. antihistamines). The negative control is a phosphate buffer solution of sodium chloride with glycerol (Control I), or a bicarbonate buffer solution of sodium chloride with glycerol (Control III for pollen allergens). The positive control is histaminium dichloride diluted in the ratio 1:1,000 (concentration of 1.0 mg/mL) in the isotonic NaCl solution (not included in the set). **Contraindications:** Absolute contraindication is not known. The testing is not performed in an acute febrile disease, systemic disease in the stage of acute symptoms or decompensation, acute allergic reaction or immediately afterwards, pathologic skin symptoms in the tested area (e.g. eczema, after sun tanning), usually in children below 3 years of age. The test is not recommended in pregnancy due to potential reaction which must be taken into consideration as one of possible alternatives. **Special warnings:** Prior to the testing, it is necessary to verify the concentration of allergens, appearance and usability period. The puncture is made using a sterile disposable lancet intended for the prick test. **Drug and other interactions:** Prior to the test, if allowed by a patient's health condition, the patient should not take medications with a potential effect on the skin test. It is advisable to adhere to the recommended intervals between the medication administration and a skin test performance. **Application in pregnancy and during lactation:** The testing should not be performed during pregnancy. During lactation, skin tests can only be performed upon a 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:** Expected local reactions (oedema, erythema, pruritus) are present in all positive reactions; they appear within 15 – 20 minutes after the tested allergen application. In some cases, a delayed or late reaction can appear within 5 to 6 or 24 hours after the tested allergen application in form of a diffuse swelling. Adverse reactions of the anaphylaxis type are rare. They are manifested within 20 minutes after the application. **Packaging:** A

glass bottle of the hydrolytic class I with a drop tip in a paper box, a patient information leaflet. Individual types of allergens are differentiated by coloured labels. Packaging size: 1 x 3 mL. A phosphate buffer solution of sodium chloride with glycerol (Control I) and a bicarbonate buffer solution of sodium chloride with glycerol (Control III – in pollen allergens) are included as the negative control. 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** D-AL PRICK TEST**. Last text revision date:** October 2012**.**