Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Soluprick SQ Timothy Grass (Phleum pratense) pollen 10 HEP Solution for skin-prick testing

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Standardised extract of grass allergen (*Phleum pratense*) pollen 10 HEP.
Soluprick SQ is a standardised extract of grass allergen. The biological activity is related to the concentration of allergen expressed in the unit HEP (10 HEP is equivalent to 10 mg/ml histamine dihydrochloride based on skin-prick test).
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for skin-prick testing.
A transparent colourless solution

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicinal product is for diagnostic use only.

Soluprick SQ grass allergen (*Phleum pratense*) pollen is indicated for skin-prick testing for the diagnosis of specific IgE mediated allergy to grass allergens (*Phleum pratense*and other cross-reacting grasses of the Pooideae family).

4.2 Posology and method of administration

The skin-prick test should be carried out by trained healthcare professionals, according to national regulations.
A skin-prick test is performed by administering one drop of each allergen extract epicutaneously in the surface of the skin using an ALK Lancet and performed on the volar side of the forearm or on the back.
Soluprick Positive Control (Histamine dihydrochloride 10 mg/ml) is applied as reference to evaluate the general reactivity of the skin-prick test and Soluprick Negative Control is applied to evaluate unspecific reactions. Substantial reaction to the negative control or lack of reaction to the positive control makes the test non-interpretable.
The solution is ready for use.
Paediatric population
Prick testing in children is already possible after the first year of life depending on the child's constitution, but in general should not be performed before the age of 4.
Skin-prick test technique:
- The skin-prick test is normally performed on the volar side of the forearm. Alternatively the test may be performed on the patient's back.
- The skin must be clean and dry. It is recommended to wash the test area with an alcoholic solution.
- One drop of each test solution and of the Positive and Negative Controls is applied on the skin. The drops are placed at a distance of more than 1.5 cm apart. An applicator used for one solution should never be used for another solution. Number tape may be applied in order to obtain sufficient distance between the drops and greater assurance in the evaluation of the weals. An adequate distance prevents the solutions from being mixed. The forearm should be at rest, e.g. on the corner of a table. Apply the Positive and Negative Controls at the end.
- The superficial layer of the skin is pierced through the drop perpendicular to the skin using the ALK Lancet. NB! The same lancet must not be used for more than one solution. Apply a slight, constant pressure for approximately 1 second and aim at uniform piercing. Apply the pressure for approx. 1 second, and then draw the lancet straight back. The allergen-containing drops are pierced first, then the Positive and Negative Controls.
- Surplus allergen extract should be removed with a tissue by blotting. It is important to avoid contamination between the allergens.
- The reactions are read after 15 min. A positive reaction is a weal with or without flare. Transfer the results to the test form: Mark the contour of the actual weal with a pen. Transfer the result to the test form with the adhesive side of transparent tape, after which the reaction can be read on graph paper.

- A weal with a diameter of ≥ 3 mm is considered to be a positive reaction provided this reaction is substantially larger than that of the negative control.

4.3 Contraindications

In very rare cases, systemicallergic reactions may occur. Skin-prick testing must therefore not be performed on patients on concomitant treatment with β-receptor blocking agents as these may influence efficiency of anti-anaphylactic treatment.Soluprick SQ is contraindicated if the patient is hypersensitive to phenol or any of the other ingredients in Soluprick SQ apart from the active substance.
Soluprick SQ is contraindicated in patients with acute or chronic atopic dermatitis in the area used for testing (see section 4.4)

4.4 Special warnings and precautions for use

If the patient has any diseases seriously affecting the patient´s general condition, skin lesions in the area used for testing, dermatographism, dermatitis and eczema in active stage in the area used for testing, it may influence the interpretation of the test outcome. In these cases, the back may be used or the test be postponed until the disorder is stabilised.

Due to the potential risk of systemic allergic reactions, a skin-prick test should only be carried out in the presence of an anaphylactic emergency kit, and signs of systemic reactions *should be monitored*(see section 4.8).

In case of axillary lymph node dissection, it is preferable to perform the skin tests in the opposite arm.

Decreased weal size may be observed in infants and the elderly.

4.5 Interaction with other medicinal products and other forms of interactions

Concomitant treatment with symptomatic anti-allergic agents may affect the reliability of the diagnosis.

The following is recommended:

Therapeutic agent	Interval between last given dose and Soluprick
Short-acting antihistamines	2-3 days
Long-acting antihistamines	8 weeks
Hydroxyzine	2 weeks
Ketotifen	2 weeks
Local application of potent steroid ointment	2-3 weeks

Corticosteroids in doses lower than 30 mg prednisone/prednisolone per day for up to one week do not reduce the response in the skin-prick test, whereas local application of potent steroid ointment suppresses the skin-prick test response for up to 2-3 weeks. Oral low dose of glucocorticoids (doses lower than 10 mg prednisolone per day) need not be discontinued prior to the skin-prick test.

Antidepressants may interfere with the result of the skin-prick test due to potential effect on the histamine H_1 receptors. Tricyclic antidepressants may interfere with the result of the skin-prick test for up to 2 weeks after the last administration of antidepressants. There is no corresponding knowledge of withdrawal for the other antidepressants. Therefore, the rate of elimination and the H_1 antihistamine potency of the given antidepressants should be taken into consideration. The risks of discontinuing treatment with an antidepressant should carefully be considered with the benefits of the skin-prick test.

In very rare cases, systemic allergic reactions may occur and skin-prick testing must therefore not be performed on patients in concomitant treatment with β-receptor blocking agents as these may influence efficiency of anti-anaphylactic treatment (See section 4.3).

Previous treatment with *Phleum pratense* immunotherapy may diminish the response to the test and was an exclusion criterion in the clinical trials on diagnostic performance.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of Soluprick SQ in pregnant women. This product should not be used in pregnant women unless the benefits are considered by the treating physician to outweigh the risks.

Lactation
No effects on the suckling child are anticipated since the systemic exposure of the breastfeeding woman to Soluprick SQ is negligible. Soluprick SQ can be used during breastfeeding.

4.7 Effects on ability to drive and use machines

Soluprick SQ has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects associated with the skin-prick test can be attributed to an immunological response (local and/or systemic) provoked by the allergen (see section 5.1).

Adverse reactions are divided into groups according to the MedDRA- Convention frequencies: Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), very rare (<1/10,000; not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Drug Reaction
General disorders and administration site conditions	Very common	Application site reactions, Continuously increasing diameter of the weal, cell shape changes (pseudopodia), diffuse swelling (delayed reaction).
Immune system disorders	Rare	Systemic allergic reactions such as rhinitis, conjunctivitis, urticaria, angioedema and asthma.
	Very rare	Anaphylaxis

Very commonly reported adverse reactions in patients tested with Soluprick where local allergic reactions at the site of application. The diameter of the weal is continuously increasing and cell shape changes **(**pseudopodia) may appear after the test**.** In some cases a delayed reaction in the form of a diffuse swelling may occur 6-24 hours after application of the skin-prick test.

In rare cases systemic allergic reaction, such as rhinitis, conjunctivitis, urticaria, angioedema or asthma may develop after the skin-prick test.

In very rare cases anaphylaxis may develop within minutes after the skin-prick test and requires immediate treatment with adrenaline and other intensive anaphylactic treatment.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions viathe national reporting system listed in Appendix V.

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Tests for allergic diseases.
ATC code: V 04 CL.

Soluprick SQ pollen allergens are used for specific diagnosis by skin-prick testing. The extracts are a mixture of molecules with high-molecular weight. An immediate allergic reaction develops within 10-20 minutes, characterised by development of a weal and flare. The weal and flare reactions provoked by an IgE-mediated immunological response are mainly caused by the binding between the applied allergen and specific IgE on the mast cells. This results in an activation of these cells and release of vasoactive mediators, e.g. histamine, prostaglandin D2 (PGD2) and leukotriene C4 (LTC4).

5.2 Pharmacokinetic properties

Neither the dose applied at the skin-prick test nor the route of administration indicates that Soluprick SQ pollen allergens result in a clinical effect after systemic absorption. No attempt has been made to explain the break-down of the individual components. The amount of solution absorbed into the outermost layer of the skin in a skin-prick test corresponds to approximately 3 x 10^{-3} µl.

5.3 Preclinical safety data

In subcutaneous single- and 28 day repeat-dose toxicity studies in mice and rats, the NOAELs were 60 mg/kg and 0.6 mg/kg, respectively. The corresponding safety factors exceed 100 millions with respect to the single-dose study and 1 million with respect to the repeat-dose study.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Sodium chloride
Glycerol
Phenol
Sodium hydroxide or hydrochloric acid (for pH adjustment)
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.
Once opened; the product may be stored for a maximum of 6 months at 2°C – 8°C (after which it must be discarded).

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).

6.5 Nature and contents of container

2 ml of solution in a vial (glass type I) closed with a stopper (halobutyl rubber) and with a screw cap (propylene). Pack size of 1.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused products or waste material should be disposed in accordance with local regulations.

7 MARKETING AUTHORISATION HOLDER

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Boge Alle 6-8
DK-2970 Horsholm
Denmark

8 MARKETING AUTHORISATION NUMBER

PA1255/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 9th June 2008
Date of last renewal: 4th December 2012

10 DATE OF REVISION OF THE TEXT

May 2014