

# 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 health care professionals, according to national regulations.

A skin-prick test is performed by administering one drop of each allergen extract on the surface of the skin using a lancet and is 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 at 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 back of the patient.
- 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 control is applied on the skin. The drops are placed with a distance of more than 1.5 cm. 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 wheals. An adequate distance prevents the different solutions from being mixed. The forearm should be at rest, e.g. on the corner of a table. Apply the Positive and Negative control at the end.
- The superficial layer of the skin is pierced through the drop perpendicular to the skin using the lancet. Note! 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 sec., and then draw the lancet straight back. The allergen-containing drops are pierced first, then the Positive and Negative control.

- Surplus allergen extract is removed with a tissue. It is important to avoid contamination between the allergens.
- The reactions are read after 15 min. A positive reaction is a wheal with or without flare. Transfer the results to the test form: Mark the contour of the actual wheal. 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 wheal with a diameter of  $\geq 3$  mm is considered to be a positive reaction provided this reaction is substantially larger than that of the negative control

### 4.3 Contraindications

Hypersensitive to and of the excipients listed in section 6.1.1

### 4.4 Special warnings and precautions for use

#### Severe systemic allergic reactions

Due to the rare risk of severe systemic allergic reactions, testing with Soluprick SQ should only be performed when the prerequisites for emergency treatment of anaphylaxis are available and the patient should be kept under supervision for at least 30 minutes (see section 4.8). One option for treating severe systemic allergic reactions is adrenaline. The effects of adrenaline may be reduced in patients treated with beta-blockers.

Patients with cardiac disease may be at increased risk in case of severe systemic allergic reactions due to less ability to compensate for hypotension and hypoxia. Clinical experience with Soluprick SQ in patients with cardiac disease is limited.

In patients with severe allergic symptoms caution should be exercised and skin prick testing possibly postponed.

#### Asthma

Patients with uncontrolled asthma may be at increased risk in case of systemic allergic reactions. If possible, patients with uncontrolled asthma should be stabilised before testing with Soluprick SQ.

#### Skin disorders or lesions in the area used for testing

Skin prick testing with Soluprick SQ should only be performed on healthy skin without lesions.

If the patient has any skin disorders in the area for testing such as dermographism, atopic dermatitis, eczema, skin infections or sun damage, it may influence the interpretation of the test outcome. If applicable, the back may be used or the skin prick test postponed until the disorder is stabilised.

#### General condition of the patient

Diseases seriously affecting the general condition of the patient may influence the test outcome. In these cases, skin prick testing with Soluprick SQ should be postponed until the patient is stabilised.

#### Special populations

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

### 4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed for Soluprick SQ.

Concomitant treatment with other medications may suppress the immediate reaction to skin prick testing with Soluprick SQ and could lead to a false-negative result.

The following is recommended:

- Treatment with short-acting antihistamines should be stopped at least 3 days before skin prick test is performed and treatment with longer-acting antihistamines about 1 week prior to testing.
- Topical application of highly effective glucocorticoids in the area of testing can suppress the reaction to the skin prick test for up to 3 weeks (depending on the strength of the preparation).
- Systemically administered corticosteroids in low doses (up to 10 mg prednisolone equivalents per day) need not be discontinued prior to skin prick testing. Long-term use of higher doses may influence the reaction to the skin prick test for up to 3 weeks after discontinuation. For short-term use of corticosteroids (>10 mg prednisolone equivalents per day), skin testing should not be performed any earlier than 1 week after discontinuation.

Other medications may influence the skin prick test result through an antihistamine-like effect (such as tricyclic antidepressants). Caution should be taken when interpreting the skin prick test results and elimination-time as stated in the relevant product information should be considered e.g. treatment with omalizumab interferes with the results, if taken 4-6 weeks prior to the skin prick test.

Previous or concomitant treatment with allergen immunotherapy may diminish the test response to the respective allergen.

In the rare case of a severe systemic allergic reaction when testing with Soluprick SQ the effects of adrenaline may be reduced in patients treated with beta-blockers (see section 4.4).

#### 4.6 Fertility, pregnancy and lactation

##### Pregnancy

There are no or limited amount of data from the use of Soluprick SQ in pregnant women. Soluprick SQ should not be used in pregnant women unless the benefits are considered by the treating physician to outweigh the risks.

##### Breastfeeding

No clinical data are available for the use of Soluprick SQ during breastfeeding. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to Soluprick SQ is negligible.

##### Fertility

There are no clinical data with respect to fertility for the use of Soluprick SQ.

#### 4.7 Effects on ability to drive and use machines

SoluprickSQ has no or negligible influence on the ability to drive and use machines.

#### 4.8 Undesirable effects

##### Summary of safety profile

Undesirable effects associated with Soluprick SQ can be attributed to an immunological response (local and/or systemic) provoked by the allergen. Commonly reported adverse reactions in patients tested with Soluprick SQ were mild to moderate local allergic reactions at the site of application. In rare cases, systemic allergic reactions may develop after the skin prick test (see Section 4.4).

##### List of adverse drug reactions

Adverse reactions associated with Soluprick SQ obtained from 13 clinical trials (including more than 60 different allergen species) in adult and paediatric patients and/or spontaneous reporting are tabulated below. Allergen species tested in clinical trials include *Phleum pratense* and other grasses, *Betula verrucosa* and other trees, house dust mites (*Dermatophagoides farinae*, *Dermatophagoides pteronyssinus*), *Artemisia vulgaris* and other weeds, *Alternaria alternata* and other moulds, *Felis domesticus*, *Canis familiaris* and other animal epithelia, and various food allergens including different fruits, vegetables, nuts, flour, fish, and milk.

Adverse reactions are divided into groups according to the frequencies: Very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse Drug Reaction
Immune system disorders	Not known	Anaphylactic reaction
Eye disorders	Uncommon	Conjunctivitis
Respiratory, thoracic and mediastinal disorders	Uncommon	Rhinitis
	Rare	Asthma <sup>#</sup>
Skin and subcutaneous tissue disorders	Uncommon	Urticaria
	Not known	Angioedema
General disorders and administration site conditions	Common	Application site reaction*

*\*Application site reactions include symptoms (beyond the expected wheal formation) such as application site pruritus, swelling/oedema, urticaria, erythema, pain, induration, inflammation, irritation, rash, and warmth*

*#Cases of acute worsening of asthma symptoms have been reported*

#### Description of selected adverse drug reactions

Commonly reported adverse reactions in patients tested with Soluprick SQ were local allergic reactions at the site of application. Local application site reactions were reported in 1.6% of the patients in the clinical trials.

Reactions with wheals of continuously increasing size, possibly with pseudopodia formation, may occur within 20 minutes after application. In some cases, a delayed reaction in form of a diffuse swelling may occur within 24 hours after the skin prick test.

In very rare cases (frequency not known) anaphylaxis may develop within minutes after the skin prick test and require immediate treatment with adrenaline and other intensive anaphylactic treatment.

#### Paediatric population

Clinical safety data for the paediatric population <18 years of age are limited, however, clinical and post-marketing experience indicate that frequency, type, and severity of adverse reactions in children are comparable to adults.

#### 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 via the national reporting system at:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

## **4.9 Overdose**

Undesirable effects, in the form of exaggerated pharmacological effects, may occur with incorrect administration.

## **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 wheal and flare. The wheal 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 D<sub>2</sub> (PGD<sub>2</sub>) and leukotriene C<sub>4</sub> (LTC<sub>4</sub>).

### **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  $3 \times 10^{-3}$  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**

ALK-Abello A/S  
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**

December 2025