Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Soluprick Negative control, Solution for skin prick test

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

No active ingredient.
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for skin prick test.
A clear aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

This medicinal product is for diagnostic use only.

Positive and negative control of skin prick tests for diagnosis of specific IgE-mediated allergy.

4.2 Posology and method of administration

A skin prick test (SPT) is performed by administering a drop of the product on the surface of the skin. The skin is penetrated using a lancet. The skin prick test may be perfomed 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.

Skin prick testing should be performed by experienced personnel only.

Instructions for use

- 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 dry and clean. It is recommended to wash the test area with an alcoholic solution.
- Each test solution and the Positive and the Negative control are applied in droplets on the skin placed with a distance of more than 1.5 cm. The forearm should be at rest. Apply the Positive and the Negative control at the end.
- The superficial layer of the skin is pierced through the droplet perpendicular to the skin using a 1 mm tip standardised lancet. A new lancet must be used for each allergen.
- Apply a slight, constant pressure for approximately 1 second. Draw the lancet straight back.
- Surplus allergen extract is removed with a tissue. It is important to avoid contamination between the allergens.
- The reactions are read after 15 minutes.
- A positive reaction is a weal with or without erythema.
- The result may be transferred to a test form as follows: Mark the contour of the actual wheal. Transfer the result to the test form with the adhesive side of transparent tape, where after the reaction can be read on graph paper.
- A wheal with a diameter of at least 3 mm is considered to be a positive reaction.
- For the Negative Control no reaction is expected. In case of a positive reaction with the Negative Control the skin prick test in general must be regarded as not reliable.

4.3 Contraindications

Acute or chronic atopic dermatitis in the area used for testing.
Soluprick Positive and Negative Controls are contraindicated if the patient is hypersensitive to phenol or any other excipient in Soluprick Positive and Negative Controls.

4.4 Special warnings and precautions for use

Caution should be carried out if the patient is suffering from one or more of the following conditions: 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 (test should be postponed). These conditions may influence the interpretation of the test outcome.

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

In extremely rare cases systemic allergic reactions may occur after skin prick testing with active allergen extracts.
For skin prick tests with active allergan performed concomitantly with Soluprick Positive and Negative Control, an emergency kit with a ready for use adrenaline syringe must always be available. The concomitant use of beta-blocking agents may influence efficiency of anti-anaphylactic treatment (e.g. adrenaline).

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant treatment with anti allergic symptomatics may affect the result of the test.

It is recommended that patients who are going to have a skin-prick test performed discontinue treatment with:

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

Corticosteroids in doses lower than 30 mg of prednisone/prednisolone per day for up to one week do not reduce the response of the skin prick test.

Long-term treatment with oral low dose glucocorticoids (doses lower than 10 mg of prednisolone per day) need not be discontinued prior to the skin- prick test. Locally applied steroid drugs must be avoided in the area use for testing 2-3 weeks prior to the test.

4.6 Fertility, pregnancy and lactation

The risk of performing skin prick test during pregnancy must be carefully evaluated together with the patient in order to identify the specific clinical need for identifying the trigger allergen during the period of pregnancy. Skin prick testing with Soluprick Positive and Negative Controls may be performed during lactation.

4.7 Effects on ability to drive and use machines

Soluprick Positive and Negative Controls have no influence on the ability to drive and use machines.

4.8 Undesirable effects

Soluprick Positive Control (histamine dihydrochloride) will cause a local reaction with development of weal and erythema with local itching after the test. In some cases a slight local pain may appear. (See Section 4.2).

Administration site reactions:

MedDRA SOC	**Frequency**
General disorders and administration site conditions	**Common (≥1/100 to <1/10): Pain**

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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

No event of overdose is reported upon correct usage. Undesirable effects, in the form of exaggerated pharmacological effects, can be caused by wrong administration.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacodynamic group: Tests for allergic diseases.
ATC Code: V 04 CL

Soluprick Positive Control: Histamine will cause an imitation of the local allergic reaction within 10-20 minutes, characterised by development of a weal and erythema. The weals and erythema are caused by the vaso-active effect of histamine.

5.2 Pharmacokinetic properties

Soluprick Positive Control is applied epicutaneously to obtain a local reaction. Soluprick Negative Control is used to evaluate unspecific reactions. The amount of solution applied epicutaneously during skin prick testing corresponds to 3 x 10-3 µl.

5.3 Preclinical safety data

No non-clinical studies have been carried out.
Many years of clinical experience with the compounds used in the formulation confirms an acceptable level of safety in the amounts administered to the patient.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium dihydrogen phosphate dihydrate
Disodium phosphate dihydrate
Sodium chloride
Glycerol
Water for Injections
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
6 months after first opening of the vial.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).

6.5 Nature and contents of container

2 ml solution in a clear type I glass vial closed with a bromobutyl rubber stopper and a propylene screw cap.

6.6 Special precautions for disposal and other handling

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

7 MARKETING AUTHORISATION HOLDER

ALK-Abelló A/S
Bøge Allé 6-8
DK-2970 Hørsholm
Denmark

8 MARKETING AUTHORISATION NUMBER

PA1255/3/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th April 2006

Date of last renewal: 11th November 2008

10 DATE OF REVISION OF THE TEXT

April 2014