SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Soluprick Positive Control, 10 mg/ml, Solution for skin-prick test

Soluprick Negative Control, Solution for skin-prick test

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Soluprick Positive Control: Histamine dihydrochloride 10 mg/ml.

Soluprick Negative Control: 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 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.

Skin-prick testing should be performed by experienced personnel only.

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.

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 at least 1.5 cm. apart. The forearm should be at rest. Apply the positive and the negative control after the active tests.
- The superficial layer of the skin is pierced through the droplet perpendicular to the skin using a 1 mm tip standardized 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 wheal 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 Soluprick Negative Control no reaction is expected. In case of a positive reaction with the Soluprick Negative Control the skin-prick test in general must be regarded as not reliable.

4.3 Contraindications

Hypersensitivity to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Soluprick Positive Control

Skin disorders or lesions in the area used for testing

Skin prick testing with Soluprick Positive Control 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 or eczema, 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 Positive Control should be postponed until the patient is stabilised.

Special populations

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

Soluprick Negative Control
Skin disorders or lesions in the area used for testing
Skin prick testing with Soluprick Negative Control 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 or eczema, 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 Negative Control should be postponed until the patient is stabilized.

4.5 Interaction with other medicinal products and other forms of interaction

Soluprick Positive Control
No interaction studies have been performed for Soluprick Positive Control.
Concomitant treatment with other medications may suppress the immediate reaction to skin prick testing with Soluprick Positive Control 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.

Soluprick Negative Control
Not applicable.

4.6 Fertility, pregnancy and lactation
Pregnancy:

There are no or limited amount of data from the use of Soluprick Positive and Negative Control in pregnant women. Soluprick Positive and Negative Control 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 Positive and Negative Control during breastfeeding. No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to Soluprick Positive and Negative Control is negligible.

Fertility:
There is no clinical data with respect to fertility for the use of Soluprick Positive and Negative Control.

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

Summary of safety profile
Soluprick Positive Control
Skin prick testing with Soluprick Positive Control (histamine dihydrochloride) will cause a local reaction with development of wheal and erythema with local itching after the test. In some cases (frequency not known), a slight pain at the application site may appear.

Soluprick Negative Control
In some cases (frequency not known), a slight pain at the application site may appear.

List of adverse drug reactions
Not applicable.

Description of selected adverse drug reactions
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 Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

Soluprick Negative Control
Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Test for allergic diseases

ATC Code: V04 CL

Soluprick Positive Control: Histamine will cause an imitation of the local allergic reaction within 10-20 minutes, characterized by development of a wheal and erythema. The wheals 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 at skin-prick testing corresponds to 3×10^{-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
Disodium hydrogen phosphate
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

The solution is ready for use.

7 MARKETING AUTHORISATION HOLDER

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Bøge Allé 6-8
DK-2970 Hørsholm
Denmark

8 MARKETING AUTHORISATION NUMBER(S)

PL 10085/0019

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/11/2024

10 DATE OF REVISION OF THE TEXT

22/08/2025