

1045761 (02/2014) **PACKAGE LEAFLET: INFORMATION FOR THE USER**

**SOLUPRICK® POSITIVE  
CONTROL, 10 mg/ml,  
Solution for Skin-prick test  
Histamine Dihydrochloride  
AND  
SOLUPRICK® NEGATIVE  
CONTROL,**

**Solution for Skin-prick Test**

**Read this leaflet before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Soluprick® is and what it is used for?
2. Before you use Soluprick®
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**1. WHAT SOLUPRICK® IS AND WHAT IT IS USED FOR?**

Soluprick® is a solution for skin prick testing.

Soluprick® Positive and Negative Control are for diagnostic use only. They are used as a reference with other skin prick tests to determine which substances cause your allergic reaction.

The Histamine Dihydrochloride in the Soluprick® Positive Control will produce a hard raised weal, which may be surrounded by a red area and this is called a positive response. This response is compared with the responses from substances that you might be allergic to.

Soluprick® Negative Control will usually not cause any reaction, and is used to ensure that positive responses are not caused by the prick of the lancet.

**2. BEFORE YOU USE SOLUPRICK®**

**Do not use Soluprick® Positive and Negative control**

- If you have ever experienced a bad reaction when using this product or any other product containing phenol or any other ingredient contained in the solution (see section 6).
- If you have skin problems (atopic dermatitis) in the area in which the skin prick test is to be applied.

Please inform your doctor if any of these statements apply to you.

**Take special care with Soluprick® Positive and Negative control**

Some conditions can affect the results of the skin prick test, therefore please tell your doctor or health professional before the skin prick test is carried out if:

- Your general health condition is seriously affected by any disease;
- You suffer from active eczema or other skin diseases in the area of the skin used for testing;
- You have had a lymph node in the armpit removed.

In extremely rare cases an anaphylactic reaction (a severe reaction throughout the body that is recognized by weals, itching, shortness of breath and fainting) may occur after skin prick testing with substances that you are allergic to. Therefore your doctor or health professional should have an appropriate emergency kit available before conducting the skin prick test, to be able to take adequate emergency measures which may include injection of adrenaline.

Beta-blocking medication (used by example for high blood pressure and several heart diseases) may influence the efficacy of adrenaline, so please tell your doctor if you are taking beta-blocking medication.

**Using other medicines**

Please tell your doctor or health professional if you are taking or have recently taken any other medicines including those obtained without a prescription.

Some medicines can affect the results of the skin prick test, therefore: Please tell your doctor or health professional before the skin prick test is carried out if you are taking any of the following medicines

- Short-acting antihistamines (usually used to treat hayfever or skin hives), such as fexofenadine, ebastine, promethazine within the last two to three days;
- Long-acting antihistamines (usually used to treat hayfever or skin hives), such as cetirizine, clemastine, hydroxyzine, promethazine, loratadine within the last week;
- Antidepressants (of the type called 'tricyclic antidepressant'), such as amitriptyline, clomipramine, imipramine, maprotiline, nortriptyline, dosulepin and doxepin, within the last week;
- Corticosteroids (sometimes called steroids), such as prednisolone and prednisone, which may be taken

to treat arthritis, inflammation of blood vessels (called vasculitis), asthma and other diseases

- Corticosteroid creams and ointments (which are used to treat eczema and other types of skin inflammation) such as hydrocortisone, triamcinolone acetonide, flucortolone 21-pivalate, betamethasone 17-valerate, betamethasone dipropionate and fluocinolone acetonide that you have applied to your skin within the last two to three weeks

**Pregnancy and breast-feeding**

In case of pregnancy, ask your doctor, pharmacist, or health professional for advice before having a skin prick test done.

Skin prick testing can be performed if you are breast feeding.

**Driving and using machines**

Soluprick® Positive and Negative controls have no known negative effect on the ability to drive and use machines.

**3. HOW TO USE SOLUPRICK®**

Prick testing may be performed in children over the age of one if the child is able to tolerate the procedure, but in general should not be performed before the age of 4. Your doctor or health professional will carry out the skin prick test for you. The procedure is as follows:

- The skin prick test is usually carried out on the inner side of the forearm. Alternatively the test can be done on your back.
- Your skin must be dry and clean and may be disinfected with alcohol by the doctor or healthcare professional.
- The test solutions, Soluprick® Positive control and Soluprick® Negative control are applied in droplets on the skin at an appropriate distance from each other.
- The top layer of the skin is pierced by the doctor or nurse with a lancet through the droplets.
- The reaction is read after 15 minutes. A positive reaction is a pale small raised swelling or weal with a red edge.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Soluprick® can cause side effects, although not everybody gets them.

Soluprick® Positive Control will cause the expected local effects associated with histamine. The Positive control will produce a hard raised weal, which may be surrounded by a red area and local itching.

In some cases you may experience slight pain at the skin prick test control site.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the MHRA Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE SOLUPRICK®**

- Keep out of the reach and sight of children.
- The clinic/hospital will store the skin prick test solution.
- Store in a refrigerator (2°C – 8°C).
- Do not use Soluprick® after the expiry date which is stated on the label and carton.
- Soluprick® should be used within six months after first opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

**6. FURTHER INFORMATION**

The active substance in Soluprick® Positive Control is Histamine Dihydrochloride. There is no active substance in Soluprick® Negative Control.

The solutions also contain Glycerol, Phenol, Disodium phosphate dihydrate, Sodium dihydrogen phosphate dihydrate, Sodium Chloride, Sodium hydroxide, Hydrochloric acid and Water for Injection.

**What Soluprick® looks like and the content of the pack**  
Soluprick® is supplied in a glass vial containing 2 ml clear solution.

The vial is closed with a rubber stopper and a screw cap.

**Marketing Authorisation Holder:**

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

**Manufacturer:**

ALK Abelló S.A.  
Miguel Fleita 19  
E-28037 Madrid  
Spain

**This medicinal product is authorised in the member states of EEA under the following names:**

Soluprick® Positive Control, Soluprick® Negative Control

**Marketing Authorisation Number:** PL 10085/0019

**This leaflet was last revised in: February 2014**

This leaflet will be made available in formats appropriate for the blind and partially sighted people upon request. Please contact: ALK-Abelló Ltd, 1 Manor Park, Manor Farm Road, Reading Berkshire, RG2 0NA. United Kingdom. Tel: 0118 903 7940