(05/2012)

PATIENT INFORMATION LEAFLET SOLUPRICK SQ **10 HEP**

Solution for Skin Prick Testing

Grass pollen, tree pollen, weed pollen, animal hair and dander and house dust mites

1. WHAT YOU SHOULD KNOW ABOUT SOLUPRICK SQ

Please read this leaflet carefully before you start treatment with Soluprick SQ. Soluprick SQ is a solution for skin prick testing (SPT). It is used in the diagnosis of specific allergenic diseases. If you have any questions or are in any doubt about anything, please ask your doctor or nurse.

2. WHAT IS THE SKIN PRICK TESTING FOR?

Soluprick SQ is used to check if you have an allergy to one of the following groups of allergens:

Grass pollen Tree pollen Weed pollen Animal hair and dander House dust mites

See section number 7

3. BEFORE YOU ARE GIVEN YOUR SKIN **PRICK TEST**

- Are you regularly taking Beta-blockers to control your blood pressure?
- Have you any skin problems in the area to be used for
- Are you allergic to any of the ingredients in Soluprick SQ?
- Are you taking, antihistamines, hydroxyzine, ketotifen, tricyclic antidepressants or using steroid ointment?
- If the answer to any or all of the above questions is YES, TELL YOUR DOCTOR/NURSE BEFORE HE/SHE GIVES YOU SOLUPRICK SQ

4. HOW WILL YOU BE GIVEN THE SKIN PRICK TEST?

Prick testing in children is already possible after the first year of life, depending on the child's constitution.

While in general Skin Prick Testing before the age of 4 is not performed, your specialist may decide to do this test in a child under 4 years if he/she considers that it is necessary. Your specialist will discuss this with you.

This medicinal product will be administered exclusively by trained healthcare professionals who will give you instructions

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 nurse or doctor
- Test preparations and the controls are applied in droplets on the skin at an appropriate distance from each other (a numbered tape may be used).
- The top layer of the skin is pierced by the doctor/nurse with an ALK 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.

5. AFTER YOU HAVE BEEN GIVEN THE SKIN **PRICK TEST**

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

Normally a Skin Prick Test does not cause any problems but occasionally some people may get side effects such as:

- · A continuously spreading weal may be formed very commonly (in more than 1 in 10 patients) at the site during the first 10-20 minutes after application of the allergen.
- Very commonly (in more than 1 in 10 patients) local widespread swelling and redness may happen 6-24 hours after the application of the allergen.

If you experience any of these side effects, and they stay or become troublesome, tell your doctor or pharmacist. If you get any other unusual or unexpected side effect, you should tell your doctor or pharmacist at once.

Anaphylactic reaction

In very rare cases (less than 1 in 10,000 patients) an anaphylactic reaction/shock may occur after skin-prick test with active allergens. Symptoms that often signal the beginning of a severe anaphylactic reaction (side effect) might be flushing, intense itching in palms, feet and other areas of the body (like nettle rash), difficulty in breathing, a sense of

heat, general discomfort and agitation may develop after a few seconds or minutes.

If this happens your doctor or health professional will have an emergency kit available with a 'ready for use' adrenaline

TELL YOUR DOCTOR/NURSE IMMEDIATLEY IF YOU FEEL ANY OF THESE CHANGES. He or she will be able to give you the right treatment at once to make you feel well.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

6. HOW SHOULD THE SKIN PRICK TEST BE STORED?

- The clinic/hospital will store the Skin Prick Test, solution.
- This medicine should be kept in a refrigerator (between 2°C and 8°C) out of the reach and sight of children, as the medicine could harm them.
- Do not freeze the solution.
- Keep the vials in the outer carton to protect it from light.
- Do not use the skin prick test solution after the expiry date, which is printed on the carton and label.

7. WHAT IS IN THE MEDICINE?

Soluprick SQ is a solution for skin prick testing that contains an extract of specific allergen. The allergen is the substance that causes the allergic disease. Soluprick SQ also contains the inactive ingredients, disodium phosphate, sodium dihydrogen phosphate, phenol, sodium chloride, glycerol and water for injections.

The following individual allergens are available:

Grass pollen: Timothy Grass. Tree pollen: Silver Birch. Weed pollen: Mugwort.

Animal hair and dander: Horse Dander, Dog Hair, Cat Hair

House dust mites: Dermatophagoides farinae,

Dermatophagoides pteronyssinus

Each single allergen is provided in a 2 ml glass vial.

The strength of the products is 10 HEP

The biological activity of Soluprick SQ is related to the reaction in the skin of an allergic patient measured relative to a histamine dihydrochloride solution.

8. MANUFACTURER AND PRODUCT LICENCE **HOLDER**

Product Licence Holder

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

Manufacturer

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

9. DISTRIBUTOR

ALK-Abelló Ltd. 1 Manor Park. Manor Farm Road, Reading, Berkshire, RG2 0NA United Kingdom Tel: 0118 903 7940

10. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

May 2012

11. FURTHER INFORMATION

Allergy UK Tel: 01322 619 898 www.allergyuk.org





