

PACKAGE LEAFLET: INFORMATION FOR THE USER

Soluprick Positive control, 10 mg/ml,
Solution for skin-prick test
histamine dihydrochloride

Soluprick
Negative control, Solution for skin prick test

Read all of this leaflet before you start using this medicine.
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor or healthcare professional.
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 healthcare professional.

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 test.

Soluprick Positive and Negative Controls are for diagnostic use only. They are used in a skin-prick test to determine which substances cause your allergic reaction.

Soluprick Negative Control will not cause any reaction. The Histamine Dihydrochloride in the Soluprick Positive Control will produce a hard raised patch of skin, which may be surrounded by a red area. This is a positive result and shows the doctor or healthcare professional that your skin-prick test is working. These tests are especially important if you have been using drugs that reduce the activity of skin-prick tests e.g. antihistamines, some antidepressants or strong topical steroid preparations.

2. Before you use Soluprick

Do not use Soluprick Positive and Negative Controls

- If you have ever experienced a bad reaction when using this product or any other product containing histamine dihydrochloride or any other ingredient contained in the solution
- If you have skin problems in the area the skin-prick test is to be applied
- If you are hypersensitive to phenol

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

Take special care with Soluprick Positive and Negative Controls

Some conditions can affect the result of the skin-prick test. Therefore, please tell your doctor or healthcare professional before the skin-prick test is carried out if you have any of the following conditions:

- Suffer from eczema in the active stage or other skin diseases in the area of the skin used for testing
- Have had a lymph node in an armpit removed
- Your general health is seriously affected by any disease

Using other medicines

Please tell your doctor or healthcare 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 healthcare professional before the skin-prick test is carried out if you are taking any of the following medicines:

- Short-acting antihistamines within the last two to three days
- Long-acting antihistamines within the last eight weeks
- Drugs containing hydroxyzine within the last two weeks
- Drugs containing ketotifen within the last two weeks
- Tricyclic antidepressants within the last two weeks
- Corticosteroids (steroids) in doses less than 30mg prednisone or prednisolone per day for longer than one week
- Glucocorticoids (steroids) at doses higher than 10mg prednisolone per day
- Strong topical steroid preparation applied to your skin within the last two to three weeks

Pregnancy and breast-feeding

In case of pregnancy, ask your doctor or healthcare 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

Your doctor or healthcare 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 performed 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 healthcare professional 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

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. After the test, the Positive Control will produce a hard raised patch of skin, which may be surrounded by a red area with local itching.

In some cases slight pain may appear.

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 healthcare professional.

In extremely rare cases an anaphylactic reaction (a severe reaction throughout the body that is recognised by weals, itching, difficulty breathing and fainting) may occur after skin-prick testing with active allergens. If it happens your doctor or healthcare professional will have adequate emergency kit available with a 'ready for use' adrenaline syringe.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRÁ Pharmacovigilance, website: www.hpra.ie

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. The expiry date refers to the last day of that month
- Soluprick should be used within six months after the 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 10 mg/ml. 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 of 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
DK-2970 Hørsholm
Denmark

Manufacturer:

ALK-Abelló S.A.

Miguel Fleta 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:

Soluprick Positive Control: PA1255/003/001

Soluprick Negative Control: PA1255/003/002

This leaflet was last revised in: March 2024