

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 carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Soluprick is and what it is used for
2. What you need to know before you use Soluprick
3. How to use Soluprick
4. Possible side effects
5. How to store Soluprick
6. Contents of the pack and other information

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. What you need to know before you use Soluprick

Do not use Soluprick Positive and Negative Controls

- If you are allergic to any of the ingredients in Soluprick Positive and Negative Control apart from the active substance (listed in section 6).

Please inform your doctor if this statement applies to you.

Warning and precautions

Talk to your doctor before using Soluprick Positive and Negative Control

- If you have skin problems in the area the skin-prick test is to be applied (e.g. eczema, skin infections or sun damage)
- If you suffer from a disease which is affecting your general health

Other medicines and Soluprick Positive and Negative Control

Soluprick Positive control

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 three days;
- Long-acting antihistamines within the last week;
- Steroids at doses higher than 10 mg prednisolone per day within the last three weeks;
- Strong steroid preparation applied to your skin within the last three weeks;
- Tricyclic antidepressants;
- Omalizumab (a medicine used for allergic asthma and/or inflammation of the nose and sinuses) within the last four to six weeks;

Tablet treatment with less than 10 mg prednisolone per day will not suppress the reaction to the skin-prick test.

Other medicines may interfere with the result of the skin-prick test. You should discuss with your doctor the risk of discontinuing treatment compared with the benefits of having a skin-prick test.

Soluprick negative control

Not applicable.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

There are no adequate data from the use of Soluprick in pregnant women. This product should not be used in pregnant women unless the benefits are considered by the treating physician to outweigh the risks.

Skin prick testing can be performed if you are breast-feeding, as the amount of medicine that passes into breast milk is negligible and no effects on the child are expected.

Driving and using machines

Soluprick Positive and Negative Controls have no or negligible influence 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 a lancet through the droplets.
- The reaction is read after 15 minutes. A positive reaction is a pale small raised swelling or wheal with a red edge.

If you use more Soluprick than you should

Skin prick test with Soluprick is given by a healthcare professional. In the event of an overdose, you will be monitored and treated by a healthcare professional.

4. Possible side effects

Like all medicines, this medicine 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 (frequency not known) slight pain may appear.

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 healthcare professional.

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 to the HPRA via HPRA 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 this medicine out of the sight and reach 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other 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

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Bøge Allé 6-8
DK-2970 Hørsholm
Denmark

Manufacturer:

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Fleta 19 E-28037 Madrid
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Marketing Authorisation Number:

Soluprick Positive Control: PA1255/003/001
Soluprick Negative Control: PA1255/003/002

This medicine is authorised in the Member States of European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Austria	ALK Prick Positiv Kontrolle, ALK Prick Negativ Kontrolle
Belgium	Soluprick Positieve controle, Soluprick Negatieve controle
Denmark	ALK Soluprick Positiv Kontrol, ALK Soluprick Negativ kontrol
France and Luxembourg	Soluprick contrôle Positif, Soluprick contrôle Négatif
Iceland	Soluprick Positiv Kontrol, Soluprick Negativ Kontrol
Ireland	Soluprick Positive control, Soluprick Negative control
Norway	Soluprick Positiv kontroll, Soluprick Negativ kontroll

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