

Package Leaflet: Information for the User

Prick Test Solutions Allergen Extracts for Skin Prick Testing

Read all of this leaflet carefully before you have the prick test.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- 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 Prick Test Solutions are and what they are used for**
2. **What you need to know before you are tested with Prick Test Solutions**
3. **How Prick Test Solutions will be used**
4. **Possible side effects**
5. **How to store Prick Test Solutions**
6. **Contents of the pack and other information**

1. **What Prick Test Solutions are and what they are used for**

Prick Test Solutions are preparations containing substances known as **allergens**. Allergens can trigger an allergic reaction in some people.

Prick Test Solutions are used by your doctor to help establish **which allergens (substances) you may be allergic to**. Each prick test solution contains a different allergen, your doctor will decide which ones to test you with. This leaflet applies to all allergens listed in section 6.

This medicine is for diagnostic use only (to show if the person is allergic to a particular substance).

2. **What you need to know before you are tested with Prick Test Solutions**

Do not use the Prick Test Solution if

- you know you have an **intolerance** to phenol, glycerol or any of the other non active ingredients in the test solution (listed in section 6)
- you have any **skin damage** on the area to be tested (inner or outer part of forearm)
- you are suffering from any **serious disease**
- you are **pregnant** or think you might be pregnant.

Children and adolescents

Children under the age of 1 year **must not** have the prick test.

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.

Other medicines and prick test solutions

Talk to your doctor, nurse or pharmacist **before you have the prick test** if you are taking or using:

- **Beta blockers** e.g. *Atenolol* used in the treatment of conditions such as high blood pressure and heart problems
- **Antihistamines** e.g. *Cetirizine* and *Astemizole* used in the treatment of conditions such as hayfever, rashes and swelling of the face and throat

- **Corticosteroids** e.g. *Beclometasone* used in the treatment of conditions such as asthma, running nose and nasal congestion
- **Mast Cell Stabilisers** e.g. *Sodium Cromoglicate* used in the treatment of conditions such as running nose, nasal congestion, asthma and itchy or sore eyes.

You should stop taking the following medicines before having the prick test:

- Antihistamines (except for *Astemizole*) and Mast Cell Stabilisers at least **48 hours before** having the prick test
- *Astemizole*, which you should stop taking at least **6 to 8 weeks before** having the prick test
- Corticosteroids. Talk to your doctor about **reducing your dose slowly**, so that you are no longer taking corticosteroids **48 hours before** having the prick test.

Having the prick test while taking Antihistamines, Corticosteroids and Mast Cell Stabilisers can cause **false negative** results.

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

Pregnancy, breast feeding and fertility

You **should not have** the prick test if you are pregnant, trying to get pregnant or think you might be pregnant.

You **can have** the prick test while breast feeding.

There is no anticipated effect on fertility.

Driving and using machines

Prick Test Solutions have no influence on the ability to drive and use machines.

Prick Test Solutions can contain sodium and potassium

This medicinal product contains less than 1mmol sodium (23mg) per dose, i.e. essentially ‘sodium-free’.

This medicinal product contains less than 1mmol potassium (39mg) per dose, i.e. essentially ‘potassium-free’.

3. How Prick Test Solutions will be used

The prick test will be performed under the supervision of a qualified doctor. They will be equipped with full facilities for cardiorespiratory resuscitation to deal with any severe reaction to the test.

This medicine is for intraepidermal use. This means it will be applied within the outer layer of your skin.

Having the skin prick test

- You will normally have the prick test on the inner or outer part of your forearm.
- Your skin may first be cleaned with disinfectant.
- The doctor or nurse will then mark out on your skin what allergies they will test you for, using a ball point pen.
- A drop of the test solution will be placed on your skin. The surface of your skin will then be pricked through the solution using a sharp instrument (lancet).
- **Do not rub or scratch** the site of the prick test.
- The doctor will then wait about 10 minutes before seeing if a skin reaction has occurred.

- A positive reaction to a particular Prick Test Solution shows as an area of pale raised skin (wheal) with surrounding redness (erythema).

You **must wait** in the surgery/clinic for at least **30 minutes** after the prick test. If you experience mild symptoms or signs of an allergic reaction, you will be kept under observation until these symptoms have completely disappeared.

If you have any further questions on the use of this product, please ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, Prick Test Solutions can cause side effects, although not everybody gets them.

Get urgent medical treatment immediately if you notice a severe allergic reaction, known as anaphylactic shock, after having the prick test. Symptoms include:

- General itching and feeling of heat – especially affecting scalp, mouth, throat, palms or soles
- Severe wheezing, or noisy or difficult breathing
- Severe hives/nettle rash
- Swelling of the lips or throat
- Pale or greyish skin colour
- A fast heart beat
- Faintness or collapse

Anaphylactic shock can develop a few minutes after having the prick test, often before a local reaction has appeared. An emergency kit will be available. Anaphylactic shock is exceptionally rare during skin prick testing.

You may experience **delayed side effects** a few hours after exposure to the allergen, though this is rare. If this happens please **see your doctor immediately**.

Tell your doctor, nurse or pharmacist **immediately** if you get a **runny nose, rash, have difficulty breathing or you are wheezing**.

Side effects in children are expected to be the same as in adults.

You may get **swelling or irritation** at the **site of the prick test**, later on after the test. This is **nothing to be concerned about** and can be treated with oral antihistamines or a topical corticosteroid. **Ask your pharmacist** for more advice.

Reporting of side effects (UK)

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 the Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Reporting of side effects in other countries:

Malta: Please report side effects to: Malta Medicines Authority, Website:

www.medicinesauthority.gov.mt/adrportal

Albania: Please report side effects to: National Agency for Drugs and Medical Devices, Website:

www.akbpm.gov.al/formulari-raportimi/

South Korea: Please report side effects to: Ministry of Food and Drug Safety, Website:

<https://nedrug.mfds.go.kr>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Prick Test Solutions

- Keep out of the sight and reach of children.
- Once opened this medicine may be stored for a maximum of 24 months.
- Store in a refrigerator between 2 °C and 8 °C. Do not freeze.
- Do not use after the expiry date which is stated on the vial label. The expiry date refers to the last day of that month.
- Do not use if there are any visible signs of deterioration.
- Medicines should not be disposed of via wastewater or household waste. Your doctor or nurse will dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Prick Test Solutions contain:

- Each prick test solution contains one of the active substances listed below. The **active substances** are:

Pollens

B2 Grass pollens 10,000 DU/ml ODC in 2 ml
B3 Tree pollens 2.5%* in 2 ml
B5 (mixed weeds and shrubs pollen) 2.5%* in 2 ml
Birch pollen 10,000 DU/ml ODC in 2 ml
Hazel pollen 10,000 DU/ml ODC in 2 ml
Nettle pollen 10,000 DU/ml in 2 ml
Plantain pollen 10,000 DU/ml ODC in 2 ml
Poplar pollen 10,000 DU/ml in 2 ml

Moulds

Alternaria alternata 10,000 DU/ml ODC in 2 ml
Cladosporium cladosporioides 10,000 DU/ml ODC in 2 ml

Fur and Feathers

Cat fur 10,000 DU/ml ODC in 2 ml
Dog hair 10,000 DU/ml ODC in 2 ml
Horse hair 10,000 DU/ml in 2 ml
Mixed feathers 150%* in 2 ml

House Dust Mites

D. farinae 10,000 DU/ml ODC in 2 ml
D. pteronyssinus 10,000 DU/ml ODC in 2 ml

Foods

Egg, whole 10,000 DU/ml ODC in 2 ml
Milk 50%* in 2 ml
Wheat grain 10%* in 2 ml

* Nominal Value

- The **non active ingredients** are:

Phenol
Sodium Chloride†
Disodium Phosphate Dodecahydrate†
Potassium Dihydrogen Phosphate†
Sodium Dihydrogen Phosphate Dihydrate†
Glycerol
Water for Injections.

†Only present in some Prick Test Solutions

Information relevant to other countries: please refer to the individual vial label for relevant information.

What Prick Test Solutions look like and the contents of the pack

The colours of the individual Prick Test Solutions vary depending on the allergen, e.g. pollens tend to be yellowish, whilst dusts and moulds are shades of brown.

The solutions come in glass vials with a dropper applicator. The vials contain 2 ml of solution.

Marketing Authorisation Holder and Manufacturer
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