

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

Birch Pollen (*Betula spp*) 10,000 DU/ml ODC  
Solution for skin prick test

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Birch Pollen (*Betula spp*) 10,000 DU/ml ODC in 2 ml

For the full list of excipients see Section 6.1.

### 3. PHARMACEUTICAL FORM

Solution for skin prick test  
A clear solution.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

This medicinal product is indicated for the diagnosis of allergic (IgE – mediated) diseases (type 1 in the classification of Coombs and Gell).

#### 4.2 Posology and method of administration

Taking a careful case history is a vital part of the investigation of a patient with allergy symptoms since it will usually identify those allergens most likely to be clinically significant. Skin testing will help to confirm the significance of the likely causative allergens and establish their relative importance.

##### Posology

##### *Paediatric population*

Prick testing in children is possible after the first year of life depending on the child constitution, but in general should not be performed before the age of 4.

##### Method of administration

The tests are usually carried out on the volar surface of the forearm: In conditions of extreme outdoor temperatures allow acclimatisation to room temperature: If test area has been cleaned with water, alcohol etc, wait at least two minutes to allow skin circulation to return to normal).

Clean the skin with soap and water if necessary – but do not sterilise with organic solvents or strong antiseptics.

A ballpoint pen may be used to mark the skin (with suitable symbols) adjacent to planned test sites to identify the allergen and control solutions used.

The colours of the individual skin testing solutions vary depending on the characteristics of the raw material involved, e.g. pollens tend to be yellowish whilst dusts and moulds in particular, are shades of brown.

Since each vial is used more than once, aseptic precautions must be sufficient to avoid the risk of microbial contamination.

Place one drop of each of the required test solutions on previously marked skin areas, which should be at least 4 cm apart. Puncture with a needle or blood lancet through the test solution. There should be no bleeding. (If the needle/ lancet is re-used in an individual patient, it should be wiped thoroughly between tests to avoid carry-over of allergen.)

Blot excess fluid from the arm, taking care not to cross contaminate the test sites.

The test(s) should be accompanied by a negative control test with the solvent used for the extracts. (A positive control test with histamine solution may also be used).

### **Interpretation of skin test reactions**

Scrutinise the course of reactions at intervals. The definitive test result is read after approximately 10 minutes. A positive control test reaction presents as a pale wheal (oedema) with a surrounding halo of red (erythema).

Assess the strength of each reaction by the degree of erythema and the area of the wheal formed. Record the strength of each reaction relative to the control as follows:-

|      |   |
|------|---|
| -    | No wheal. Erythema absent or less than 1 mm diameter.                       |
| +    | Wheal absent or very slight. Erythema present, not more than 3 mm diameter. |
| ++   | Wheal not more than 3 mm diameter, with associated erythema.                |
| +++  | Wheal between 3 mm and 5 mm diameter, with erythema.                        |
| ++++ | Any larger reaction, possibly with pseudopodia                              |

Although some patients will give a reaction to the control solution, they will usually give significantly larger reactions to the allergens to which they are clinically sensitive. In recording the reactions to these allergens, an allowance should be made for the size of the control solution.

### **4.3 Contra-indications**

Prick testing solutions must not be used for intradermal testing.

The prick test solutions must not be used in the presence of any of the conditions listed below:

Any skin lesions in the area to be used for testing.  
Any diseases seriously affecting the patients' general condition.  
Hypersensitivity to any of the excipients listed in Section 6.1.  
Pregnancy – please refer to Section 4.6 Fertility, pregnancy and lactation.

#### **4.4 Special warnings and special precautions for use**

- Skin tests should not be performed during treatment with betablockers.
- An emergency medical kit and adrenaline/epinephrine should always be kept at hand when giving any prick test.
- Using a needle/lancet, or a rinsing solution, for more than one patient carries the risk of transmitting blood-borne viruses, and must not occur.
- The patient should be instructed not to rub or scratch the test site.

#### **Anaphylactic shock**

Systemic anaphylaxis following prick testing is almost unknown. The operator should have adequate experience to differentiate anaphylactic reaction from other reactions more likely to be seen during skin testing, e.g. vasovagal, hyperventilation etc, and to manage those reactions appropriately.

#### *Warning symptoms **include:***

Tingling, itching and burning sensations on the tongue, in the mouth, throat or particularly on the palms and soles. This may be immediately followed by shock with cyanosis, hypotension, tachycardia, bronchospasm and unconsciousness.

Further clinical signs are: anxiety, restlessness, urticaria, dizziness, laryngeal oedema with dyspnoea, nausea and vomiting, respiratory and cardiac arrest.

Severe and potentially life-threatening reactions require fast and effective emergency treatment.

The treatment of allergic reactions is based on current medical guidelines.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Used as concomitant therapy with anti-allergic agents like antihistamines, corticosteroids and medicines with an incidental antihistamine action, this solution for skin prick test may cause false negative results. As such, medicines should be discontinued at least 48 hours – and astemizole 6-8 weeks – before testing.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

Skin testing should not be carried out during pregnancy.

##### Breast-Feeding

Skin testing may be carried out during lactation.

### Fertility

There are no fertility data available. No effects on fertility are anticipated.

## **4.7 Effects on ability to drive and use machines**

Birch Pollen (Betula spp) 10,000 DU/ml has no influence on the ability to drive and use machines.

## **4.8 Undesirable effects**

Adverse allergic reactions are rarely encountered during skin prick testing. Patients should be warned that late local reactions may occur and that they are no cause for concern and can be treated with oral antihistamine or topical corticosteroid.

In certain circumstances unduly severe or prolonged reactions may occur in patients who have a high degree of sensitisation. In exceptionally rare cases there may be generalised adverse reactions even amounting to serious systemic reactions (anaphylactic shock). For these reasons an 'emergency kit' (with an adrenaline/epinephrine syringe) must be immediately available. As a precautionary measure, each patient must be kept under observation for at least 30 minutes, after which time a medical assessment is made.

### **Reactions**

**Local:-** Such as swelling or irritation. These may require symptomatic treatment if they are severe or persist.

### **Systemic:-**

*Mild:* such as rhinitis or urticaria.

*Severe:* Such as wheezing or bronchospasm.

Anaphylactic shock can develop a few minutes after administration, often before a local reaction has appeared (see section 4.4).

Typical warning symptoms of anaphylactic shock are described in section 4.4.

In exceptionally rare cases, adverse reactions may occur even a few hours after exposure to the allergen. When in doubt especially after the appearance of systemic reactions the patient should seek medical advice / treatment immediately.

### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

## **4.9 Overdose**

If the product is used incorrectly (e.g. intracutaneous use), allergic reactions may be more severe. In such cases, the risk of anaphylactic shock is increased.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Allergens

ATC Classification: V04C L Tests for allergic diseases

In an antigen-antibody reaction, the allergens present in prick test solutions react with allergen-specific IgE sensitised mast cells in the patient's skin. This reaction liberates mediators, in particular histamine, from the mast cells. These produce erythema at the test site, together with a demarcated wheal, sometimes accompanied by the formation of pseudopodia.

### **5.2 Pharmacokinetic properties**

Not applicable.

### **5.3 Preclinical safety data**

No further information of relevance.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Phenol

Sodium Chloride

Disodium Phosphate Dodecahydrate

Sodium Dihydrogen Phosphate Dihydrate

Glycerol

Water for injections

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf-life**

3 years.

### **6.4 Special precautions for storage**

Store in a refrigerator (2°C - 8°C).

Do not freeze.

### **6.5 Nature and contents of container**

2.0 ml Type 1 Ph.Eur. glass dropper container with polyethylene screw cap with pipette and black rubber teat.

**6.6 Special precautions for disposal**

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7. MARKETING AUTHORISATION HOLDER**

Allergy Therapeutics (UK) Ltd  
Dominion Way  
Worthing  
West Sussex  
BN14 8SA  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

PL 17087/0014

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation date: 29 September 1999  
Date of latest renewal: 28 September 2005

**10. DATE OF REVISION OF TEXT**

01/2017