SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

B2 Grass Pollens 10,000 DU/ml ODC
Solution for skin prick test

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of B2 Grass Pollens contains 10,000 DU/ml ODC* in 2 ml solution

B2 contains equal proportions of 12 purified allergen extracts of pollen from the following grasses:

Bent	*Agrostis Tenuis/Capillaris*
Brome	*Bromus spp*
Cocksfoot	*Dactylis Glomerata*
Dogstail	*Cynosarus Cristatus*
Fescue, Meadow	*Festuca pratentis*
Foxtail, Meadow	*Alopercurus pratentis*
Meadow Grass	*Poa Pratentis*
Oat (False) Grass	*Arrhenatherum Elatius*
Rye Grass	*Lolium Perenne*
Sweet Vernal	*Anthoxanthum Odoratum*
Timothy	*Phleum Pratense*
Yorkshire Fog	*Holcus Lanatus*

* ODC optimal diagnostic concentration

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Solution for skin prick test.

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.

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

For cutaneous use.

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 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.

Method of administration
Tests are usually carried out on the volar surface of the forearm: In conditions of extreme outdoor temperatures allow acclimatisation to room temperature.

Clean the skin with soap and water if necessary – but do not sterilise with organic solvents or strong antiseptics. If the test area has been cleaned with water or alcohol etc, wait at least two minutes to allow skin circulation to return to normal.

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.

Place one drop the required test solution on the 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.

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

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 the reaction at intervals. The definitive test result is read after approximately 10 minutes. A positive 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. Contraindications

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 precautions for use

- Skin tests should not be performed during treatment with betablockers.
- An emergency 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. Interactions 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 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

B2 Grass Pollens 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

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
Disodium Phosphate Dodecahydrate
Sodium Dihydrogen Phosphate Dihydrate
Glycerol
Water for Injections
Sodium Chloride

6.2. Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store in a refrigerator (2ºC - 8ºC). Do not freeze.

6.5. Nature and contents of container

2.0 ml Type 1 Ph.Eur. glass vial with dropper applicator.

6.6. Special precautions for disposal

No special requirements for disposal.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 17087/0030

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 September 2006

10. DATE OF REVISION OF THE TEXT

01/2017