B2 GRASS POLLENS 10,000 DU/ml ODC

(Grass pollen B2)

PL 17087/0030

UKPAR

TABLE OF CONTENTS

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LAY SUMMARY

The MHRA today granted Allergy Therapeutics (UK) Ltd a Marketing Authorisation (licence) for the medicinal product B2 Grass Pollens 10,000 DU/ml ODC (PL 17087/0030), which are grass pollen extracts. B2 Grass Pollens are cutaneous solutions containing standardised allergen extracts. The active ingredient is made up of equal proportions of 12 purified pollen allergen extracts which contains the relevant allergens. The B2 Grass Pollen species are *Agrostis Tenuis/Capillaris* (Bent), *Bromus spp* (Brome), *Dactylis glomerata* (Cocksfoot), *Cynosarus Cristatus* (Dogstail), *Festuca pratensis* (Meadow Fescue), A*lopecurus pratensis* (Meadow Foxtail), *Poa Pratentis* (Meadow Grass), *Arrhenatherum Elatius* (Oat Grass), *Lolium Perenne* (Perennial Rye Grass), *Anthoxanthum Odoratum* (Sweet Vernal), *Phleum Pratense* (Timothy Grass), and *Holcus Lanatus* (Yorkshire Frog). Grass pollens are the major case of IgE-mediated allergic disease. This medicine is prescription only and may be administered to children

B2 grass pollens is used in the diagnosis of specific IgE-mediated allergic diseases (type I in the classification of Coombs and Gell) via a skin prick test which is usually performed on the volar surface of the forearm. A droplet of B2 grass pollens is applied to the skin along with a droplet of a negative control preparation (solvent used for the extract) and a droplet of a positive control preparation (histamine solution). The skin is pierced with a lancet through each of the droplets and any skin reactions are observed after approximately 10 minutes. If the patient is allergic to any of the substances in the droplets, then a visible inflammatory reaction will usually occur, the strength of which will be recorded.

Persons with IgE-mediated diseases, or atopy, have a hereditary predisposition to produce IgE antibodies against common environmental allergens such as plant pollens, mold spores, drugs (i.e. penicillins), foods, insect stings and animal products. Hayfever is an example of a common minor allergy whose symptoms are caused by airborne pollen.

The clinical data presented to the MHRA demonstrated that B2 grass pollens accurately diagnoses adults and children with specific IgE mediated allergic diseases via the skin prick test and there were no unexpected safety concerns. It was therefore judged that the benefits of using this product outweigh the risks; hence a Marketing Authorisation has been granted.

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(Grass pollen B2)

PL 17087/0030

SCIENTIFIC DISCUSSION

INTRODUCTION

Based on the review of data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product B2 Grass Pollens (PL 17087/0030) to Allergy Therapeutics (UK) Ltd on 13th October 2006. The product is prescription only and intended for adults and children.

This was an abridged, national application for B2 Grass Pollens, containing the following standardized pollen extracts: *Agrostis Tenuis/Capillaris* (Bent), *Bromus spp* (Brome), *Dactylis glomerata* (Cocksfoot), *Cynosarus Cristatus* (Dogstail), *Festuca pratensis* (Meadow Fescue), A*lopecurus pratensis* (Meadow Foxtail), *Poa Pratentis* (Meadow Grass), *Arrhenatherum Elatius* (Oat Grass), *Lolium Perenne* (Perennial Rye Grass), *Anthoxanthum Odoratum* (Sweet Vernal), *Phleum Pratense* (Timothy Grass), and *Holcus Lanatus* (Yorkshire Frog). The application was submitted under article 10.1 (a) (i) of Directive 2001/83/EC as amended. This new diagnostic was brought in to replace the existing diagnostic (PL 17087/0011) which is to be discontinued. B2 Grass Pollens is similar to PL 17087/0011, with the exception that the allergen (B2 grass pollens) has been reduced in strength from 2.5% w/v (PL 17087/0011) to 0.25% w/v (PL 17087/0030).

B2 Grass Pollens is used in the diagnosis of specific IgE-mediated allergic diseases and may be used in adults and children.

B2 Grass Pollens is for administration by the skin prick test only on the forearm of the patient.

PHARMACEUTICAL ASSESSMENT

BASIS FOR APPLICATION

National Abridged Simple application (line extension) under article 10.1 (a) (i) of Directive 2001/83/EC as amended.
Change or addition of a new strength/potency.

SUPPORTING EVIDENCE

Application form
SPC, labels and patient information leaflet and technical leaflet
Finished product and drug product specifications
Manufacturer's license
Complete CTD Module 3

BACKGROUND

This product is for the diagnosis of allergic (IgE-mediated) diseases and contains a number of different grass allergens. The product is similar to PL 17087/0011, with the exception that the allergen (B2 grass pollens) has been reduced in strength from 2.5% w/v (PL 17087/0011) to 0.25% w/v (PL 17087/0030). The concentration was changed following a clinical study to determine the optimal diagnostic concentration for various allergens. The new diagnostic (PL 17087/0030) will replace the existing diagnostic (PL 17087/0011), which will be discontinued. The proposed shelf life is 36 months at 2ºC to 8ºC.

EVALUATION

The product is similar to PL 17087/0011, with the exception that the allergen (B2 grass pollens, Monocotyledonous Angiosperms) has been reduced in strength from 2.5% w/v (PL 17087/0011) to 0.25% w/v (PL 17087/0030), a 10-fold reduction in concentration. There are no changes to the formulation of the skin prick test solution. There are no changes to the raw materials or suppliers. There are no other changes to the method of manufacture or specifications.

The concentration was changed following a clinical study to determine the optimal diagnostic concentration for various allergens. This study showed that the optimal diagnostic concentration for the B2 grass pollens allergen was 0.25% w/v. The clinical study, in addition to analytical standardisation, showed that the B2 grass pollens product needed to be reformulated at a lower concentration in order to achieve an optimum weal size for diagnosis. To reflect the optimisation of the product strength, the B2 grass pollen is labelled as 10,000 DU/ml ODC (optimal diagnostic concentration).

Stability data was provided using two batches of B2 grass pollens 0.25% w/v prick test formulation in the marketed containers. Sufficient evidence was provided to support the proposed shelf life of 36 months at 2ºC to 8ºC. The product was shown to be stable under these conditions.

These stability studies did not include protein and allergen profiles, but assays for these parameters have been developed in line with the Ph Eur Allergen Products monograph (01/2005:1063) and will be used for batch release and any further GMP studies. The company has committed to test further batches as part of the GMP stability programme.

TSE suitability
Details for TSE suitability were provided in line with the Commission Directive 1999/82 and guideline EMEA/410/01 Rev2. There is no risk from pollens (vegetable).

CONCLUSION
The change in the B2 grass pollens cutaneous solution, to reduce the concentration of the allergen (B2 grass pollens, Monocotyledonous Angiosperms) from 2.5% w/v (PL 17087/0011) to 0.25% w/v (PL 17087/0030), is acceptable. The potency of the B2 grass pollen extract (determined by inhibition ELISA) remained within specification for 36 months at 2ºC to 8ºC. This is in keeping with the proposed shelf life of 36 months at 2ºC to 8ºC.

DECISION – This application can be approved.

PHARMACEUTICAL ASSESSOR
DATE :- 29th November 2005

CLINICAL ASSESSMENT

BASIS FOR APPLICATION
National Abridged Simple application (line extension) under article 10.1 (a) (i) of Directive 2001/83/EC as amended.
Change or addition of a new strength/potency.

SUPPORTING EVIDENCE
Application form
SPC, labels and patient information leaflet and technical leaflet
Finished product and drug product specifications
Manufacturer's license
Complete CTD Module 3
Clinical Study Report BDU/510

BACKGROUND
This product is for the diagnosis of allergic (IgE-mediated) diseases and contains a number of different grass allergens. The product is similar to PL 17087/0011, with the exception that the allergen (B2 grass pollens) has been reduced in strength from 2.5% w/v (PL 17087/0011) to 0.25% w/v (PL 17087/0030).

EVALUATION
The concentration was changed following a clinical study (BDU/510) which showed that the optimal diagnostic concentration for the B2 grass pollens allergen was 0.25% w/v. The clinical study, in addition to analytical standardisation, showed that the B2 grass pollens product needed to be reformulated at a lower concentration in order to achieve an optimum weal size for diagnosis. To reflect the optimisation of the product strength, the B2 grass pollen will be labelled as 10,000 DU/ml ODC (optimal diagnostic concentration).

CONCLUSION
The change in the B2 grass pollens cutaneous solution, to reduce the concentration of the allergen (B2 grass pollens, Monocotyledonous Angiosperms) from 2.5% w/v (PL 17087/0011) to 0.25% w/v (PL 17087/0030), is acceptable.

DECISION – Approved

MEDICAL ASSESSOR
DATE :- 4th October 2006

PRE-CLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of B2 Grass Pollens are well defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

EFFICACY

B2 Grass Pollens is used in the diagnosis of specific IgE-mediated allergic diseases via a skin prick test. No new or unexpected safety concerns arose from this application.

The SPC, PIL and labeling are satisfactory.

PRE-CLINICAL

No new preclinical data have been supplied with this application and none are required for an application of this type.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable, no significant clinical safety concerns were identified, and some benefit has been shown to be associated with B2 Grass Pollens. The risk benefit is therefore considered to be positive.

B2 GRASS POLLENS 10,000 DU/ml ODC

(Grass pollen B2)

PL 17087/0030

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the marketing authorisation application on 13th June 2005.

2 The MHRA completed its assessment of the application on 6th October 2006.

3 The application was determined on 13th October 2006. .

B2 GRASS POLLENS 10,000 DU/ml ODC

(Grass pollen B2)

PL 17087/0030

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome
25.09.07	Type II National	To alter the density of the materials for the pipette/screw-cap assembly.	Granted 04.12.07

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

B2 Grass Pollens 10,000 DU/ml ODC

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of B2 Grass Pollens contains 10,000 DU/ml ODC* in 2ml 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 full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cutaneous extract.

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

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.

The taking of 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.

Depending on the patient's constitution, prick testing is feasible from the age of one year, but in general skin testing is initiated at the age of 4-5 years.

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).

<u>Interpretation of skin test reactions</u>
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 weal (oedema) with a surrounding halo of red (erythema).

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

-	No weal. Erythema absent or less than 1 mm diameter.

+	Weal absent or very slight. Erythema present, not more than 3 mm diameter.
++	Weal not more than 3 mm diameter, with associated erythema.
+++	Weal 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.
Any skin lesions in the area to be used for testing.
Any diseases seriously affecting the patient's general condition.
Known hypersensitivity to any of the excipients contained (see section 6.1)
Pregnancy – Please refer to Section 4.6 Pregnancy and lactation.

4.4. Special warnings and precautions for use

As far as possible, skin tests should not be performed during treatment with betablockers.
Adrenaline Injection B.P. (Adrenaline 1 in 1,000) 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 on no account occur.
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.
The patient should be instructed not to rub or scratch the test site.
This product is essentially 'sodium free' (see section 6.1)

4.5. Interactions with other medicinal products and other forms of interaction

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

4.6. Pregnancy and lactation

Skin testing should not be carried out during pregnancy. Skin testing may be carried out during lactation.

4.7. Effects on ability to drive and use machines

Not applicable

4.8. Undesirable effects

Adverse allergic reactions are rarely encountered during 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 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. These may be treated with anti-histamines orally, or by injection if necessary. In mild bronchospasm, a sympathomimetic bronchodilator such as salbutamol and possibly an anti-inflammatory steroid should be given. If required, 0.5ml Adrenaline Injection B.P. (adrenaline 1 in 1,000) may be given subcutaneously.

Severe: Such as wheezing or bronchospasm. 0.5ml Adrenaline Injection B.P. (adrenaline 1 in 1,000) should be given intramuscularly close to the prick test site. A sympathomimetic bronchodilator and an anti-inflammatory steroid should be given.

Anaphylactic shock can develop in a few seconds to minutes, often before a local reaction has appeared.

If anaphylaxis occurs, treat as follows:

Treatment of anaphylaxis:
Anaphylactic shock is characterised by bronchospasm, laryngeal oedema, urticaria and shock.

1. The patient should be laid down and treated immediately.

2. 0.5ml* Adrenaline Injection B.P. (adrenaline 1 in 1,000) should be given intramuscularly without delay close to the prick test site. This should be

repeated to a total of 2ml* over 15 minutes if necessary. In extreme cases, if blood pressure is undetectable, 0.5ml* Adrenaline Injection B.P. (1 in 10,000) may be given by slow intravenous injection. (A 1 in 10,000 strength solution can be prepared by adding 1ml of the 1 in 1,000 solution to 9ml of saline).

3. If bronchospasm is marked, a salbutamol (or similar bronchodilator) inhaler may be employed after adrenaline. If bronchospasm persists, 10-20 ml* of Aminophylline Injection B.P. (250 mg per 10ml) should be given by slow intravenous injection at a rate of 2ml* per minute.

4. If adequate ventilation cannot be maintained, an oral airway should be inserted and ventilation with a compressible bag initiated. In extreme cases, an emergency puncture of the crico-thyroid membrane with insertion of a large bore needle may be necessary. Oxygen should be administered and other cardio-respiratory support measures e.g. defibrillation may also be required.

5. Hydrocortisone Injection B.P. (200-400mg*) should be given intravenously as a preventative measure, in order to combat bronchospasm which occurs 6-8 hours after the initial collapse.

6. All patients experiencing an anaphylactic reaction should be admitted to hospital for close observation and monitoring for at least 24 hours.

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.

*All doses should be reduced as required for children.

4.9. Overdose

See 4.8 Undesirable Effects

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 weal, 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

Liquefied Phenol
Disodium Phosphate Dodecahydrate
Sodium Dihydrogen Phosphate Dihydrate
Glycerol
Water for Injection
Sodium Chloride

The sodium content of B2 Grass Pollens is less than 1mmol sodium (23mg) per dose; therefore it is essentially 'sodium free'.

6.2. Incompatibilities

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

6.3. Shelf life

36 Months.

6.4. Special precautions for storage

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

6.5. Nature and contents of container

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

6.6. Special precautions for disposal

No special requirements. 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

12/10/2006

10 DATE OF REVISION OF THE TEXT

12/10/2006

Patient Information Leaflet

B2 GRASS POLLENS 10,000 DU/ml ODC

(Grass pollen B2)

PL 17087/0030

ALLERGEN EXTRACTS FOR SKIN PRICK TESTING

This leaflet tells you about prick-test solutions which are used for the diagnosis of allergies. Please read it carefully. If there is anything you do not understand, or if you want to know more about the tests, ask your doctor.

Keep this leaflet, you may want to read it again.

What are prick-test solutions?

Prick-test solutions contain substances extracted from such things as pollen, house dust mites, fur and feathers. These allergens cause an allergic reaction in some people.

The allergen extracts used for your skin prick-testing will consist of one or more of the following allergens*. The doctor will decide what to use after he has talked to you about your problem:

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

Moulds
Alternaria alternata 10,000 DU/ml ODC
Aspergillus fumigatus 10,000 DU/ml
Cladosporium cladosporoides 10,000 DU/ml ODC
Penicillium chrysogenum 10,000 DU/ml

Fur and Feathers
Cat fur 10,000 DU/ml ODC
Dog hair 10,000 DU/ml ODC
Horse hair 10,000 DU/ml
Mixed feathers 150% w/v

House Dust Mites
D. farinae 10,000 DU/ml ODC
D. pteronyssinus 10,000 DU/ml ODC

Foods
Egg whole 10,000 DU/ml ODC
Milk 50% w/v
Wheat grain 10% w/v

* All concentrations are approximate.

As well as the allergen extracts, the solutions may also contain other ingredients. Phenol, glycerol and water are present in all; sodium chloride, disodium phosphate dodecahydrate and sodium dihydrogen phosphate dihydrate are only present in certain solutions. The solutions may be slightly coloured for some of the allergen extracts.

The various solutions are supplied to your doctor in vials containing 2ml of product.

Who makes prick-test solutions?

Product Licence holder and manufacturer: Allergy Therapeutics (UK) Ltd., Dominion Way, Worthing, West Sussex, BN14 8SA.

What are prick-test solutions used for?

Prick-test solutions are used by your doctor to help establish whether or not certain allergens might be causing your condition.

Why is your doctor using prick-test solutions?

Your doctor is using the prick-test solutions to try to find out what might be causing your problem. If you are allergic to any of the solutions selected, and it can be more than one, a small raised lump (a weal) will form on your skin where you have been tested. The size of the weal will help the doctor work out how allergic you are.

Before having the prick-test

Do you have skin damage at the test site?
Are you suffering from a serious disease?
Are you allergic to phenol or glycerol, or any other ingredients in the test solutions?
Are you or do you think you may be pregnant?
Are you taking any anti-allergy drugs (antihistamines or steroids)?
Are you taking any medicines for high blood pressure (beta-blockers)?

If you think the answer to any of these questions is YES, tell your doctor BEFORE you have the prick-test. The doctor will decide if you are able to have the prick-test.

Always tell your doctor about any other medicines you are taking. This includes any medicines that you buy, as well as those prescribed by your doctor.

Having the prick-test

Prick-testing is possible from the age of one year, but in general begins at the age of 4-5 years.

The normal site for prick-testing is the inside of the arm. Prior to undertaking the test, it is normal for the skin to be cleaned using soap and water or something similar.

The test site will normally be marked out using a ballpoint pen. This is to enable the doctor to identify where certain solutions have been used.

The test is undertaken by placing a drop of the test solution on the skin. A needle or lancet (pointed surgical knife) will be used to prick the solution onto the surface of the skin. The doctor will wait approximately 10 minutes and then review the skin reaction. The size of the reaction can be measured and this helps the doctor determine your sensitivity to the particular allergen.

After having the prick-test you will have to wait in the surgery for at least 30 minutes. Tell the doctor at once if you feel unwell.

What unwanted effects might I have?

It is normal for the test to cause the skin to redden and to itch. It is important not to rub or scratch the affected area.

Side effects are extremely rare, however, it is possible that you may experience side effects.

You may have allergic symptoms:

Running nose, sneezing
Itching eyes
Eczema-type rash
Itchy lumps (urticaria/hives/nettle rash)
Wheezing

If you have these symptoms, or any other unusual symptoms, contact your doctor at once.

Labelling

B2 GRASS POLLENS 10,000 DU/ml ODC

(Grass pollen B2)

PL 17087/0030

B2 Grass Pollens 10,000 DU/ml ODC

Proposed vial label. Label is created by overprinting a plain, yellow bordered label. The expiry date is also added to the label.

GRP. B2 POLLENS
GRASSES
10,000 DU/ml ODC LOT NO.
4100-002-043
Allergy Therapeutics (UK) Ltd
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C – 8°C)
Testing solution (2ml) Preservative Phenol 0.5% (W/V)

B2 Grass Pollens 10,000 DU/ml ODC

Carton Labelling text:

Allergy Therapeutics (UK) Limited logo
ALLERGEN EXTRACTS FOR SKIN PRICK TESTING

*This carton contains:

B2 Grass Pollens 10,000 DU/ml ODC **PL 17087/0030**
Order reference no.

WARNING: Must **NOT** be used for intradermal testing.
For details of allergen extracts, expiry date(s) and batch reference(s): See label(s) on vial(s).
Contents: Each vial contains 2ml of solution
Preservative: Phenol Ph. Eur. 0.5% w/v. Other ingredients: glycerol, water for injections. Some extracts also include: sodium chloride, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate. Sodium content < 23mg per dose (See leaflet enclosed)
Store at 2ºC - 8ºC in a refrigerator. Do not freeze.

POM

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

Marketing Authorisation Holder: Allergy Therapeutics (UK) Ltd., Worthing, West Sussex BN14 8SA, UK.

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*This section of the carton labelling will cover the number of replacement products requested by the physician.
1-5 allergens may be provided. The full product name and PL number are overprinted onto this label for each of the allergens provided.