STANDARDISED ALLERGEN EXTRACTS FOR SKIN PRICK TESTING SERIES 1

(DERMATOPHAGOIDES PTERONYSSINUS, NETTLE POLLEN, PLANTAIN POLLEN, GRASS POLLEN B2, WEEDS MIXED AND SHRUB POLLEN B5, COTTON FLOCK, HAY DUST, DERMATOPHAGOIDES FARINAE, STRAW DUST, TREE POLLEN B3, BIRCH POLLEN, HORSE HAIR, CAT FUR, DOG HAIR, RABBIT FUR, SHEEP WOOL, FEATHERS MIXED, ALTERNARIA ALTERNATA, CLADOSPORIUM CLADOSPORIOIDES)

PL 17087/0031

UKPAR

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(DERMATOPHAGOIDES PTERONYSSINUS, NETTLE POLLEN, PLANTAIN POLLEN, GRASS POLLEN B2, WEEDS MIXED AND SHRUB POLLEN B5, COTTON FLOCK, HAY DUST, DERMATOPHAGOIDES FARINAE, STRAW DUST, TREE POLLEN B3, BIRCH POLLEN, HORSE HAIR, CAT FUR, DOG HAIR, RABBIT FUR, SHEEP WOOL, FEATHERS MIXED, ALTERNARIA ALTERNATA, CLADOSPORIUM CLADOSPORIOIDES)

PL 17087/0031

LAY SUMMARY

The MHRA today granted Allergy Therapeutics (UK) Ltd a Marketing Authorisation (licence) for the medicinal product Standardised Allergen Extracts for Skin Prick Testing Series 1 (PL 17087/0031), which is a combination of different allergens. Standardised Allergen Extracts for Skin Prick Testing Series 1 are cutaneous solutions containing standardised allergen extracts. The active ingredient is made up of 19 standardised allergen extracts of pollen, hair and dust which contain the relevant allergens. The Standardised Allergen Extracts for Skin Prick Testing Series 1 species are Alternaria alternata (10,000U/ml), Birch pollen (10,000U/ml), Cat fur (10,000U/ml), Cladosporium cladosporoides (10,000U/ml), Cotton flock (150%w/v), Dermatophagoides farinae (10,000U/ml), Dermatophagoides pteronyssinus (10,000U/ml), Dog hair (10,000U/ml), Feathers mixed (150%w/v), Grass pollen B2 (10,000U/ml), Hay dust (150%w/v), Horse hair (10,000U/ml), Nettle pollen (10,000U/ml), Plantain pollen (10,000U/ml), Rabbit fur (10,000U/ml), Sheep wool (10,000U/ml), Straw dust (150%w/v), Tree pollen B3 (2.5%w/v) and Weeds mixed and shrub pollen B5 (2.5%w/v). This medicine is prescription only and may be administered to children

Standardised Allergen Extracts for Skin Prick Testing Series 1 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 Standardised Allergen Extracts for Skin Prick Testing Series 1 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 Standardised Allergen Extracts for Skin Prick Testing Series 1 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.

STANDARDISED ALLERGEN EXTRACTS FOR SKIN PRICK TESTING SERIES 1

(DERMATOPHAGOIDES PTERONYSSINUS, NETTLE POLLEN, PLANTAIN POLLEN, GRASS POLLEN B2, WEEDS MIXED AND SHRUB POLLEN B5, COTTON FLOCK, HAY DUST, DERMATOPHAGOIDES FARINAE, STRAW DUST, TREE POLLEN B3, BIRCH POLLEN, HORSE HAIR, CAT FUR, DOG HAIR, RABBIT FUR, SHEEP WOOL, FEATHERS MIXED, ALTERNARIA ALTERNATA, CLADOSPORIUM CLADOSPIOROIDES)

PL 17087/0031

SCIENTIFIC DISCUSSION

INTRODUCTION

Based on the review of data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product Standardised Allergen Extracts for Skin Prick Testing Series 1 (PL 17087/0031) 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 Standardised Allergen Extracts for Skin Prick Testing Series 1, containing the following standardized allergen extracts: Alternaria alternata (10,000U/ml), Birch pollen (10,000U/ml), Cat fur (10,000U/ml), Cladosporium cladosporioides (10,000U/ml), Cotton flock (150%w/v), Dermatophagoides farinae (10,000U/ml), Dermatophagoides pteronyssinus (10,000U/ml), Dog hair (10,000U/ml), Feathers mixed (150%w/v), Grass pollen B2 (10,000U/ml), Hay dust (150%w/v), Horse hair (10,000U/ml), Nettle pollen (10,000U/ml), Plantain pollen (10,000U/ml), Rabbit fur (10,000U/ml), Sheep wool (10,000U/ml), Straw dust (150%w/v), Tree pollen B3 (2.5%w/v) and Weeds mixed and shrub pollen B5 (2.5%w/v). The application was submitted under article 10.1 (a) (i) of Directive 2001/83/EC as amended. This new diagnostic kit was brought in to replace the existing kit (PL 17087/0001) which is to be discontinued. Standardised Allergen Extracts Skin Prick Testing Series 1 is similar to PL 17087/0001, with the exception that one of the allergens (B2 grass pollens) has been reduced in strength from 2.5% w/v (PL 17087/0001) to 0.25% w/v (PL 17087/0031).

Standardised Allergen Extracts for Skin Prick Testing Series 1 is used in the diagnosis of specific IgE-mediated allergic diseases and may be used in adults and children.

Standardised Allergen Extracts for Skin Prick Testing Series 1 is for administration by the skin prick test only on the forearm of the patient.

PHARMACEUTICAL ASSESSMENT

BASIS FOR APPLICATION

National Abridged Standard 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 allergens. The product is similar to PL 17087/0001, with the exception that one of the allergens (B2 grass pollens) has been reduced in strength from 2.5% w/v (PL 17087/0001) to 0.25% w/v (PL 17087/0031). The concentration was changed following a clinical study to determine the optimal diagnostic concentration for various allergens. The new diagnostic kit (PL 17087/0031) will replace the existing kit (PL 17087/0001), which will be discontinued. The proposed shelf life is 36 months at 2ºC to 8ºC.

EVALUATION

The product is similar to PL 17087/0001, with the exception that one of the allergens (B2 grass pollens, Monocotyledonous Angiosperms) has been reduced in strength from 2.5% w/v (PL 17087/0001) to 0.25% w/v (PL 17087/0031), 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 of the specifications.

The concentration was changed following a clinical study 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).

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 Standardised Allergen Extracts for Skin Prick Testing Series 1, to reduce the concentration of one of the allergens (B2 grass pollens, Monocotyledonous Angiosperms) from 2.5% w/v (PL 17087/0001) to 0.25% w/v (PL 17087/0031), is acceptable. The potency (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 17087/0001, with the exception that the allergen (B2 grass pollens) has been reduced in strength from 2.5% w/v (PL 17087/0001) to 0.25% w/v (PL 17087/0031).

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 17087/0001) to 0.25% w/v (PL 17087/0031), 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 Standardised Allergen Extracts for Skin Prick Testing Series 1 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

Standardised Allergen Extract Skin Prick Testing Series 1 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 Standardised Allergen Extracts for Skin Prick Testing Series 1. The risk benefit is therefore considered to be positive.

STANDARDISED ALLERGEN EXTRACTS FOR SKIN PRICK TESTING SERIES 1

(DERMATOPHAGOIDES PTERONYSSINUS, NETTLE POLLEN, PLANTAIN POLLEN, GRASS POLLEN B2, WEEDS MIXED AND SHRUB POLLEN B5, COTTON FLOCK, HAY DUST, DERMATOPHAGOIDES FARINAE, STRAW DUST, TREE POLLEN B3, BIRCH POLLEN, HORSE HAIR, CAT FUR, DOG HAIR, RABBIT FUR, SHEEP WOOL, FEATHERS MIXED, ALTERNARIA ALTERNATA, CLADOSPORIUM CLADOSPORIOIDES)

PL 17087/0031

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. .

STANDARDISED ALLERGEN EXTRACTS FOR SKIN PRICK TESTING SERIES 1

(DERMATOPHAGOIDES PTERONYSSINUS, NETTLE POLLEN, PLANTAIN POLLEN, GRASS POLLEN B2, WEEDS MIXED AND SHRUB POLLEN B5, COTTON FLOCK, HAY DUST, DERMATOPHAGOIDES FARINAE, STRAW DUST, TREE POLLEN B3, BIRCH POLLEN, HORSE HAIR, CAT FUR, DOG HAIR, RABBIT FUR, SHEEP WOOL, FEATHERS MIXED, ALTERNARIA ALTERNATA, CLADOSPORIUM CLADOSPIOROIDES)

PL 17087/0031

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

Standardised Allergen Extracts for Skin Prick Testing Series 1

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains purified allergen extract in 2ml solution as follows:

D. pteronyssinus 10,000 DU/ml ODC in 2ml or
Nettle pollen 10,000 DU/ml in 2ml or
Plantain pollen 10,000 DU/ml ODC in 2ml or
B2 Grass pollen 10,000 DU/ml ODC in 2ml or
B5 (mixed weeds and shrubs pollen) 2.5%* in 2ml or
Cotton flock 150%* in 2ml or
Hay dust 150%* in 2ml or
D. farinae 10,000 DU/ml ODC in 2ml or
Straw dust 150%* in 2ml or
B3 Tree pollen 2.5%* in 2ml or
Birch pollen 10,000 DU/ml ODC in 2ml or
Horse hair 10,000 DU/ml in 2ml or
Cat fur 10,000 DU/ml ODC in 2ml or
Dog hair 10,000 DU/ml ODC in 2ml or
Rabbit fur 10,000 DU/ml in 2ml or
Sheep wool 10,000 DU/ml in 2ml or
Mixed feathers 150%* in 2ml or
Alternaria alternata 10,000 DU/ml ODC in 2ml or
Cladosporium cladosporioides 10,000 DU/ml ODC in 2ml

* Nominal Value

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 whilst dusts and moulds, in particular, are shades of brown.

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 of each of the required test solutions 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.
Refer to section 4.6 Pregnancy and lactation for further information.

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.
These medicinal products contain less than 1mmol sodium (23mg) per dose, i.e. they are essentially 'sodium free'.

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

There are no data from the use of allergy testing solutions in pregnant women. The potential risk for human pregnancy is unknown and therefore this product should not be used in 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
Sodium Chloride*
Glycerol
Disodium Phosphate Dodecahydrate*
Sodium Dihydrogen Phosphate Dihydrate*
Water for Injections

*Only present in certain prick test solutions.

The sodium content 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.

Each pack contains 19 vials of purified allergen extracts as listed in section 2, plus 1 vial of negative control. Each vial contains 2 ml cutaneous solution.

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 17087/0031

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

STANDARDISED ALLERGEN EXTRACTS FOR SKIN PRICK TESTING SERIES 1

(DERMATOPHAGOIDES PTERONYSSINUS, NETTLE POLLEN, PLANTAIN POLLEN, GRASS POLLEN B2, WEEDS MIXED AND SHRUB POLLEN B5, COTTON FLOCK, HAY DUST, DERMATOPHAGOIDES FARINAE, STRAW DUST, TREE POLLEN B3, BIRCH POLLEN, HORSE HAIR, CAT FUR, DOG HAIR, RABBIT FUR, SHEEP WOOL, FEATHERS MIXED, ALTERNARIA ALTERNATA, CLADOSPORIUM CLADOSPORIOIDES)

PL 17087/0031

Patient Information Leaflet

Standardised Allergen Extracts for Skin Prick Testing Series 1 & 2

This leaflet tells you about so-called "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 your treatment, ask your doctor.

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

What are prick testing solutions?

Prick test solutions are preparations containing substances extracted from **allergens**. Allergens are substances which can cause an allergic reaction in certain people e.g. pollen, fur, feathers.

Standardised Allergen Extracts for Skin Prick Testing Series 1* consists of 2ml vials containing the individual allergens: *Alternaria alternata* 10,000 DU/ml ODC, 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, Cat Fur 10,000 DU/ml ODC, *Cladosporium cladosporioides* 10,000 DU/ml ODC, Cotton Flock 150% w/v, *D. farinae* 10,000 DU/ml ODC, *D. pteronyssinus* 10,000 DU/ml ODC, Dog Hair 10,000 DU/ml ODC, Hay Dust 150% w/v, Horse Hair 10,000 DU/ml, Feathers, Mixed 150% w/v, Nettle Pollen 10,000 DU/ml, Plantain Pollen 10,000 DU/ml ODC, Rabbit Fur 10,000 DU/ml, Sheep Wool 10,000 DU/ml and Straw Dust 150% w/v.

Standardised Allergen Extracts for Skin Prick Testing Series 2* consists of 2ml vials containing the individual allergens: *Aspergillus fumigatus* 10,000 DU/ml, *Aspergillus niger* 10,000 DU/ml, Chocolate 10% w/v, Cod 10% w/v, Cow Hair 10,000 DU/ml, Egg, Whole 10,000 DU/ml ODC, Fusarium spp 10,000 DU/ml, Hazel Pollen 10,000 DU/ml ODC, Kapok 150% w/v, Lobster 10% w/v, Milk 50% w/v, Mixed Threshings 150% w/v, *Neurospora sitophila* 10,000 DU/ml, *Penicillium chrysogenum* 10,000 DU/ml, Poplar Pollen 10,000 DU/ml, *Rhizopus stolonifer* 10% w/v, *Sporobolomyces roseus* 10% w/v and 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. Dependent upon the allergen extract the solutions may be slightly coloured.

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

Who makes prick testing solutions?

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

What are prick testing solutions used for?

Prick test solutions are used by your doctor to help establish the importance of certain allergens to your condition.

Why is your doctor using prick testing solutions?

Your doctor is using the solutions to help him with the diagnosis of your problem. The allergen extracts in the solutions trigger an allergic skin reaction, such as a rash, in those people who are allergic to the substance. These people are known as being **sensitised** to that allergen. By testing a number of substances your doctor can help find out which substances could be contributing to your condition.

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 inactive ingredients in the test solutions?
- Are you or think you may be pregnant?
- Are you taking any anti-allergy drugs (antihistamines or steroids) or 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. He 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 locations for prick testing are the inside of the arm or the back. Prior to undertaking the test, it is normal for the skin to be cleaned using soap and water or something similar.

The test location 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 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 some patients may experience side effects.

Some patients 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.

IMPORTANT: Very rarely, patients may have severe allergic symptoms, such as:

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

IF ANY OF THESE SYMPTOMS DEVELOP, GET EMERGENCY MEDICAL TREATMENT IMMEDIATELY.

How are the prick testing solutions stored?

Your doctor will store the solutions in a refrigerator at 2°C – 8°C without allowing them to freeze.

Your doctor should check that the prick test solutions have not passed their expiry date.

Keep all medicines out of the reach and sight of children.

Leaflet prepared in May 2005

Series 1 & 2 Skin Test Kits Technical Leaflet

Standardised Allergen extracts for skin prick testing Series 1 and 2

INDICATION

For the diagnosis of allergic (IgE-mediated) diseases (Type 1 in the classification of Coombs and Gell).

INTRODUCTION

Case history and skin testing

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. Allergy Therapeutics (UK) Ltd. recommend the use of the prick test method for all routine skin testing, using the solutions provided with this leaflet.

FORMULATION

Prick tests: All aqueous allergen extracts and control solutions contain 50% glycerol, 0.5% phenol as a preservative and water. 6% sodium chloride, disodium phosphate dodecahydrate and sodium dihydrogen phosphate dihydrate are only present in certain solutions. This medicine contains less than 1mmol Sodium (23mg/dose) i.e. essentially sodium free. These cutaneous solutions are supplied in polythene-capped vials containing approximately 2 ml of solution, sufficient for about 100 individual tests.
Form and appearance: The colours of 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

TECHNIQUE FOR PRICK TESTING

Route of administration

Skin prick: 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. (N.B. PRICK TESTING SOLUTIONS MUST NOT BE USED FOR INTRADERMAL TESTING.)

General Information

Adrenaline Injection BP (Adrenaline 1 in 1000) and other supportive measures must always be kept at hand when skin testing with any allergens.

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.

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.

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

Prick testing method
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.

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 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 reaction.

CONTRA-INDICATIONS, WARNINGS, ETC.
Contra-indications:
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.

Precautions:
As far as possible, skin test should not be performed during treatment with beta-blockers.
Adrenaline Injection BP (Adrenaline 1 in 1000) 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.

Side 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 syringes) 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 antihistamines 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, 0.5 ml Adrenaline Injection BP (Adrenaline 1 in 1000) may be given subcutaneously.
Severe - such as several wheezing or bronchospasm. 0.5 ml Adrenaline Injection BP (Adrenaline 1 in 1000) 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. 0.5 ml* Adrenaline Injection BP (Adrenaline **1** in **1000**) should be given intramuscularly **without delay** close to the prick test site. This should be repeated to a total of 2 ml* over 15 minutes if necessary. In extreme cases, if blood pressure is undetectable, 0.5 ml* Adrenaline (**1** in **10,000**) may be given by slow intravenous injection. (A **1** in **10,000** strength solution can be prepared by adding 1 ml of the **1** in **1000** solution to 9 ml 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 BP (250 mg per 10 ml) should be given by slow intravenous injection at a rate of 2 ml* 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 BP (200-400 mg*) should be given intravenously as a preventative measure, in order to combat bronchospasm which may occur 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.

*All dosages should be reduced as required for children.

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.

Use in pregnancy and lactation:

There are no data from the use of allergy testing solutions in pregnant women. The potential risk for human pregnancy is unknown and therefore this product should not be used in pregnancy. Skin testing may be carried out during lactation.

STORAGE CONDITIONS

Store at 2°C - 8°C (In a refrigerator)
Do not freeze

LEGAL CATEGORY

POM

PACKAGE QUANTITIES

Prick testing solutions are prepared in 2 ml multi-dose vials and provided in Series 1 and Series 2 kits as below:

Series 1	Series 2
Alternaria alternata 10,000 DU/ml ODC	*Aspergillus niger* 10,000 DU/ml
Cladosporium cladosporioides 10,000 DU/ml ODC	*Neurospora sitophila* 10,000 DU/ml
D.Pteronyssinus (House Dust Mite) 10,000 DU/ml ODC	*Rhizopus stolonifer* 10%
D.farinae 10,000 DU/ml ODC	*Penicillium chrysogenum* 10,000 DU/ml
Feathers, Mixed 150%	Fusarium spp. 10,000 DU/ml
Horse Hair 10,000 DU/ml	*Sporobolomyces roseus* 10%
Cat Fur 10,000 DU/ml ODC	*Aspergillus fumigatus* 10,000 DU/ml
Dog Hair 10,000 DU/ml ODC	Poplar Pollen 10,000 DU/ml
Rabbit Fur 10,000 DU/ml	Cow Hair 10,000 DU/ml
Sheep Wool 10,000 DU/ml	Hazel Pollen (*Corylus spp.*) 10,000 DU/ml ODC
Nettle Pollen (*Urtica dioica*) 10,000 DU/ml	Wheat Grain 10%
Plantain Pollen (*Plantago lanceolata*) 10,000 DU/ml ODC	Egg, Whole 10,000 DU/ml ODC
* B2 Grass Pollen 10,000 DU/ml ODC	Milk 50%
* B3 Tree Pollen 2.5%	Chocolate 10%
Birch Pollen (*Betula spp.*) 10,000 DU/ml ODC	Cod 10%
* B5 Mixed Weeds & Shrub Pollen 2.5%	Lobster 10%
Cotton Flock 150%	Kapok 150%
Hay Dust 150%	Mixed Threshings 150%
Straw Dust 150%	Control
Control	

** Standard Pollen Groups*

B2	-	Bent; Brome; Cocksfoot; Dogstail (Crested); False Oat (Oat Grass); Fescue (Meadow); Foxtail (Meadow); Meadow Grass; Rye Grass; Timothy Grass; Vernal (Sweet); Yorkshire Fog.
B3	-	Alder; Ash; Beech; Birch (Silver); Elm; Hazel; Oak; Plane; Poplar; Willow.
B5	-	Heather; Nettle; Plantain; Fat Hen; Mugwort; Orache.

MANUFACTURER AND PRODUCT LICENCE HOLDER

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

PRODUCT LICENCE NUMBERS

Series 1: PL 17087/0031 Series 2: PL17087/0002

DATE OF PREPARATION

Leaflet prepared in May 2005.

Labelling

STANDARDISED ALLERGEN EXTRACTS FOR SKIN PRICK TESTING SERIES 1

(DERMATOPHAGOIDES PTERONYSSINUS, NETTLE POLLEN, PLANTAIN POLLEN, GRASS POLLEN B2, WEEDS MIXED AND SHRUB POLLEN B5, COTTON FLOCK, HAY DUST, DERMATOPHAGOIDES FARINAE, STRAW DUST, TREE POLLEN B3, BIRCH POLLEN, HORSE HAIR, CAT FUR, DOG HAIR, RABBIT FUR, SHEEP WOOL, FEATHERS MIXED, ALTERNARIA ALTERNATA, CLADOSPORIUM CLADOSPORIOIDES)

PL 17087/0031

Standardised Allergen Extracts for Skin Prick Testing Series 1 – Vial Labels

1.Alternaria alternata

ALT.ALTERNATA
10,000 DU/ml ODC [Batch Number]
1100-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

2. Cladosporium Cladisporioides

CLAD.CLADOSPORIOIDES
10,000 DU/ml ODC [Batch Number]
1300-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

3. D. Pteronyssinus (House Dust Mite)

D. PTERONYSSINUS
10,000 DU/ml ODC [Batch Number]
2801-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

4. D. Farinae

D.FARINAE
10,000 DU/ml ODC [Batch Number]
2800-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

5. Feathers, Mixed

FEATHERS, MIXED
150% [Batch Number]
3202-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

6.Horse Hair

HORSE HAIR
10,000 DU/ml [Batch Number]
3203-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

7. Cat Fur

CAT FUR
10,000 DU/ml ODC [Batch Number]
3204-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

8. Dog Hair

DOG HAIR
10,000 DU/ml ODC [Batch Number]
3205-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

9. Rabbit Fur

RABBIT FUR
10,000 DU/ml [Batch Number]
3301-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

10. Sheep Wool

SHEEP WOOL
10,000 DU/ml [Batch Number]
3302-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

11. Nettle Pollen

NETTLE POLLEN
URTICA DIOICA
10,000 DU/ml [Batch Number]
4006-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

12. Plantain Pollen

PLANTAIN POLLEN
PLANTAGO LANCEOLATA
10,000 DU/ml ODC [Batch Number]
4007-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

13. B2 Grass Pollen

GRP. B.2. POLLENS
GRASSES
10,000 DU/ml ODC [Batch Number]
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)
EXPIRY MM.YYYY

14. B3 Tree Pollen

GRP. B.3. POLLENS
TREES
2.5% [Batch Number]
4200-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

15. Birch Pollen

BIRCH POLLEN
BETULA SPP
10,000 DU/ml ODC [Batch Number]
4204-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

16. B5 Mixed Weed and Shrub Pollen

GRP. B.5. POLLENS
WEED & SHRUB
2.5% [Batch Number]
4800-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

17. Cotton Flock

COTTON FLOCK
150% [Batch Number]
5802-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

18. Hay Dust

HAYDUST
150% [Batch Number]
6318-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

19. Straw Dust

STRAWDUST
150% [Batch Number]
6338-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

20. Control

CONTROL
[Batch Number]
1908-002-043
Allergy Therapeutics (UK) Ltd.
SKIN PRICK TEST
STORE IN A REFRIGERATOR (2°C - 8°C)
Testing Solution (2ml) Preservative Phenol 0.5% (W/V)
EXPIRY MM.YYYY

STANDARDISED ALLERGEN EXTRACTS FOR SKIN PRICK TESTING

Carton text:

Top Panel (lid):
Standardised Allergen extracts for skin prick testing
*Series 1

Allergy Therapeutics logo

Side Panel 1:
Standardised Allergen extracts for skin prick testing

Each vial contains 2ml of standardised prick test solution
Cutaneous solutions for skin prick testing
Directions for use: See leaflet enclosed
WARNING: Must **NOT** be used for intradermal testing.
Store at 2°C-8°C (in a refrigerator). Do not freeze

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

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

Side Panel 2:
Standardised Allergen extracts for skin prick testing

For details of allergen extracts, expiry date(s)
And batch reference(s): See label on vials.

Side Panel 3:
Preservative: Phenol Ph Eur. 0.5% w/v
Other ingredients: glycerol, water for injections.
Some extracts also include: sodium chloride, disodium phosphate dodecahydrate, sodium dihyrdogen phosphate dihydrate.
Sodium content <23mg per dose (See leaflet enclosed)

Side Panel 4:
Order reference No:

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* This will be an overlabel stating Series 1 or Series 2 as the carton is used for both Series 1 and Series 2 diagnostic kits.

Inside of lid:
Skin prick testing solutions are supplied in colour-coded vials as follows:

Notes:

1. PLEASE READ ENCLOSED LEAFLET BEFORE USE
2. FOR PRICK TESTING ONLY
3. Test solution should be stored at 2°C-8°C (in a refrigerator). Do not freeze.
4. Please note the expiry date printed on the vial labels.
5. Only minimal tightening of the screw cap is required to effect a good seal.

Allergy Therapeutics logo