SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

POLLINEX Grasses + Rye Extension Course, 2000 Standardised Units (SU)/0.5ml, suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

POLLINEX Grasses + Rye Extension Course comprises 3 pre-filled syringes or 1 pre-filled vial.

Vial/Syringe No./Colour	Concentration (Standardised Units (SU))/0.5 ml)
3 Red	2000

POLLINEX Grasses + Rye contains equal proportions of 13 selectively purified allergen extracts of pollen from the following grasses:

Foxtail (*Alopecurus pratensis*)
Crested Dogstail (*Cynosurus cristatus*)
Cocksfoot (*Dactylis glomerata*)
Rye grass (*Lolium perenne*)
Meadow grass (*Poa pratensis*)
Vernal (*Anthoxanthum odoratum*)
Fescue (*Festuca pratensis*)
Bent (*Agrostis tenuis*)
Timothy (*Phleum pratense*)
Brome (*Bromus spp*.)
Oat grass (*Arrhenatherum elatius*)
Yorkshire Fog (*Holcus lanatus*)
Cultivated Rye (*Secale cereale*)

The allergens have been converted into allergoids by treatment with glutaraldehyde and are adsorbed onto L-tyrosine. The allergen extracts are characterised and standardised through immunological and biochemical methods to ensure batch-to-batch consistent allergen content and allergenic potency. Major allergens are measured in selected extracts. Standardisation is reflected by the assignment of Standardised Units (SU).

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
A white opaque suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of seasonal allergic hay fever due to grass pollen in adults, adolescents and children from the age of 6 who have failed to respond adequately to anti-allergy drugs.

The diagnosis should be based on the careful consideration of the patient's history and allergy tests, preferably skin tests.

4.2 Posology and method of administration

Posology

POLLINEX Grasses + Rye Extension Course is presented in one 3ml multi-dose vial or three unit dose syringes.

The Extension Course consists of three injections of the maximum dose of 2000 SU/0.5ml (if the maximum dose is not tolerated, treatment can take place at a lower dose). The first injection should be given about 14 days after the last injection POLLINEX Grasses + Rye. Subsequent injections should then be given at intervals of 2-4 weeks. If the season is imminent, the interval can be reduced to 1 week.

The maximum dose of 0.5ml must not be exceeded.

The course should be completed before the onset of the grass pollen season.

Do not use during the grass pollen season.

POLLINEX Grasses + Rye Extension Course should be given after
POLLINEX Grasses + Rye for continued clinical improvement.

It is recommended that the allergy vaccine should be given in each of three successive years.

Paediatric population
For children from the age of 6 years and adolescents, the same posology regime as adults is recommended.
Pollinex Grasses + Rye Extension Course should not be used in children under 6 years of age.

Method of administration
For subcutaneous injection (see section 6.6 for instructions on handling).

It should be administered at a constant pressure by subcutaneous injection to the middle third of the lateral posterior aspect of the upper arm. The injection sites should be alternated between arms, e.g. 1st and 3rd injection in the right arm and 2nd injection in the left arm. Repeated injections at one injection site should be avoided. Do not inject into a blood vessel or intramuscularly. The patient should be instructed not to rub the injection site.

4.3 Contraindications

Contraindicated in patients with asthma because they are more likely to develop life threatening reactions.

Patients should not be given an allergy vaccine if they have febrile infections or inflammation of the respiratory tract; irreversible secondary changes of the reactive organs (emphysema, bronchiectasis etc.); severe chronic and inflammatory diseases, immunopathological conditions, active tuberculosis of the lung and eyes, severe mental disorders or are receiving beta-blocker therapy.

Hyposensitisation injections should not be given to patients with systemic or local infection or who have suffered from a febrile condition in the 24 hours preceding the intended dose, or if they have immunodeficiency or an autoimmune disease.

If tyrosine metabolism is disturbed, especially in the case of tyrosinaemia and alkaptonuria, or there is known hypersensitivity to any of the excipients listed in section 6.1), the allergy vaccine should not be used.

If the patient is pregnant/discover they become pregnant whilst receiving treatment POLLINEX Grasses + Rye Extension Course should not be started or continued during pregnancy as pregnancy may change the patient's sensitisation level to a degree that cannot be foreseen. Please refer to section 4.6 Pregnancy and lactation.

4.4 Special warnings and precautions for use

The individual tolerated dose should not be exceeded.

Treatment of patients should only be carried out where full facilities for cardio-respiratory resuscitation are immediately available.

Adrenaline (Epinephrine) Injection should always be kept at hand when giving any allergen specific immunotherapy.

Patients should be kept under observation for the first 60 minutes after each injection. This period should be extended if even mild symptoms or signs of hypersensitivity develop and patients should be maintained under observation until these have completely resolved. A severe and prolonged adverse reaction may necessitate hospital admission.

Anaphylactic shock

As with any specific immunotherapy there is a risk of anaphylactic shock.

Warning symptoms:
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.

In the event of simultaneous vaccination against viral or bacterial pathogens, there should be an interval of at least one week between the last injection of POLLINEX Grasses + Rye and the day of vaccination provided all side effects (local or systemic) have completely disappeared. The next dose of POLLINEX Grasses + Rye may be administered two weeks after the vaccination provided that all side effects to the vaccination have completely disappeared, using half of the last dose administered. Afterwards, this amount can be increased according to the dosage chart at intervals of 7-14 days.

Use with caution in patients with cardiovascular deficiency.

Patients should be warned not to eat a heavy meal immediately before an injection is due to be given.

Injections should be given at a constant pressure by the subcutaneous route. Do not inject into a blood vessel or intramuscularly. Do not rub the site of injection.

The patient should not take any strenuous physical exercise for 12 hours following the injection.

All patients should be advised to contact the doctor immediately in the event of an adverse reaction.

4.5 Interactions with other medicinal products and other forms of interaction

Concomitant therapy with symptomatic anti-allergic agents (e.g. antihistamines, corticosteroids, mast cell stabilisers) may affect the tolerance level of the patient. A reduction of the dose after discontinuing treatment with these symptomatic preparations may be required.

During hyposensitisation, exposure to the causal allergens and allergens crossreacting with them is to be avoided as far as possible.

Pollinex Grasses + Rye Extension Course is contraindicated in those receiving Beta-blockers, please refer to section 4.3.

4.6 Fertility, pregnancy and lactation

The use of POLLINEX Grasses + Rye Extension Course is contraindicated in pregnancy (see section 4.3).

4.7 Effects on ability to drive and use machines

Occasionally the injection may cause mild drowsiness; the patient should be instructed not to drive or operate machinery if this is the case.

4.8 Undesirable effects

If the injection intervals and dosage regimens are followed exactly and the dose is individually increased in an appropriate manner, allergic side reactions to treatment with the allergy vaccine are rare. They are usually mild but local and/or systemic reactions must be anticipated, in which case the treatment must be immediately discontinued. For these reasons an emergency kit should be immediately available. As a precautionary measure, each patient must be kept under observation for at least 60 minutes after injections, 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. In extremely rare cases, granuloma may be observed, especially if the injection was too superficial.

Systemic:
Mild - Such as rhinitis or urticaria.

Fatigue occasionally occurs after injection of the vaccine.

Atopic eczema may be exacerbated by hyposensitisation.

Moderate - *Severe* - Such as severe wheezing or bronchospasm.

Description of selected adverse reactions

Anaphylactic reactions/anaphylactic shock
Severe anaphylactic reactions or anaphylactic shock have been reported in individual cases. Anaphylactic shock can develop minutes after administration of any allergy immunotherapy, often before a local reaction has appeared (see section 4.4).

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

In rare cases, adverse reactions may occur even a few hours after the hyposensitisation injection, in which case the patient should inform their attending doctor before the next injection. When in doubt especially after the appearance of systemic reactions the patients 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

Symptoms:
If a patient receives an overdose of an allergy vaccine, the likelihood of an adverse reaction is increased.

Reactions are characterised by symptoms ranging from slight swelling or irritation at the site of injection to anaphylaxis.

Management:
I) See 4.8 Undesirable effects.
II) The usual precautions should be followed i.e.
Patients should be kept under medical observation for at least 60 minutes after each injection.

The patient should not take any strenuous physical exercise for 12 hours following the injection.

All patients should be advised to contact the doctor immediately in the event of a reaction.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: allergens
ATC Classification: V01A A02

Immunotherapy with POLLINEX Grasses + Rye Extension Course is recommended for patients who are sensitive to specific pollens. The effectiveness of immunotherapy in reducing symptoms has been established by controlled, blinded studies.

The specific pollen allergens incorporated in POLLINEX Grasses + Rye Extension Course have been modified by glutaraldehyde treatment and adsorbed onto tyrosine with the result that allergenicity is reduced (thus increasing tolerance) while maintaining immunogenicity (related to efficacy).
Although the immunological events are not clearly understood, the production of antigen specific IgG antibody, suppression of specific IgE and decreased mediator (histamine) release from basophils are important factors.
Therapeutic effects of specific pollens immunotherapy are allergen-specific and dose dependent.

5.2 Pharmacokinetic properties

POLLINEX Grasses + Rye Extension Course contains glutaraldehyde-modified extracts of specific pollen from grasses and rye adsorbed onto L-tyrosine.
Adsorption onto L-tyrosine ensures that the allergoids are released more slowly. This results in a prolonged and efficient desensitising effect and improves tolerance. L- tyrosine is a natural amino acid, which is fully metabolised in the body.

5.3 Preclinical safety data

No further information of relevance.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

L-Tyrosine
Liquefied 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. Remove from refrigerator 2-3 hours before use.

6.5 Nature and contents of container

The 3.0 ml vial is made from clear neutral glass (Type I, Ph. Eur.) fitted with a

chlorobutyl bung, aluminium seals and coloured flip top.

The syringes are 1.0ml syringes made from clear neutral glass (Type I, Ph. Eur.) with a polypropylene plunger rod and a butyl plunger.

A pack of POLLINEX Grasses + Rye Extension course contains:

Either:
1 multi-dose vial containing 1.5ml suspension in the following concentration:
Vial No. 3. (red) with 2000 SU/0.5 ml

Or:
3 pre-filled unit dose syringes containing 0.5ml of suspension as follows:
Syringe No. 3. (red) with 2000 SU/0.5 ml

A combination pack which includes the Primary Treatment course (PL 17087/0005) is also available.

Packs containing the product in vials also contain empty syringes and needles suitable for dispensing the product.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The pack should be removed from the refrigerator 2-3 hours before use and warmed to room temperature.

POLLINEX Grasses + Rye Extension Course is a white opaque suspension. During storage a white deposit with colourless supernatant may form. Therefore, before use it is important to ensure that the syringe/vial is thoroughly shaken to ensure that all of the sediment is evenly resuspended.

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

8. MARKETING AUTHORISATION NUMBER

PL 17087/0006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27 August 1998
Date of latest renewal: 26 April 2005

10 DATE OF REVISION OF THE TEXT

02 March 2016