SOLUPRICK SQ WEED POLLEN *PARIETARIA JUDAICA* (PELLITORY OF THE WALL) 10 HEP SOLUTION FOR SKIN PRICK TEST 2ML PER VIAL

(Parietaria judaica)

PL 10085/0028

UKPAR

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SOLUPRICK SQ WEED POLLEN *PARIETARIA JUDAICA* (PELLITORY OF THE WALL) 10 HEP SOLUTION FOR SKIN PRICK TEST 2ML PER VIAL

(Parietaria judaica)

PL 10085/0028

LAY SUMMARY

The MHRA today granted ALK-Abelló A/S a Marketing Authorisation (licence) for the medicinal product Soluprick SQ Weed Pollen *Parietaria judaica* (PL 10085/0028), which is a weed pollen. Soluprick SQ Weed Pollen *Parietaria judaica* are glycerinated preparations containing standardised allergen extracts dissolved in equal parts of buffered saline and sterile glycerol. The active ingredient is a partly purified pollen allergen extract which contains the relevant allergens. The Soluprick SQ Weed Pollen species is *Parietaria judaica* (Pellitory of the wall). This medicine is prescription only and may be administered to children

Soluprick SQ Weed Pollen *Parietaria judaica* are used in the diagnosis of specific IgE mediated allergic diseases via a skin prick test which is usually performed on the forearm but also sometimes on the back of the patient. A droplet of Soluprick SQ Weed Pollen *Parietaria judaica* is applied to the skin along with a droplet of a reference preparation and a droplet of a control preparation. The skin is pierced with a lancet through each of the droplets and any skin reactions are observed after 15 minutes. If the patient is allergic to any of the substances in the droplets, then a visible inflammatory reaction will usually occur.

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

The clinical data presented to the MHRA demonstrated that Soluprick SQ Weed Pollen *Parietaria judaica* 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.

SOLUPRICK SQ WEED POLLEN *PARIETARIA JUDAICA* (PELLITORY OF THE WALL) 10 HEP SOLUTION FOR SKIN PRICK TEST 2ML PER VIAL

(Parietaria judaica)

PL 10085/0028

SCIENTIFIC DISCUSSION

INTRODUCTION

Based on the review of data on quality, safety and efficacy the UK granted a marketing authorisation for the medicinal product Soluprick SQ Weed Pollen *Parietaria judaica* (PL 10085/0028) to ALK-Abelló A/S on the 12th July 2007. The product is prescription only and intended for adults and children.

This was a simple abridged, national application for Soluprick SQ Weed Pollen *Parietaria judaica*, submitted under Article 10c of Directive 2001/83/EC. Soluprick SQ Weed Pollens are aqueous solutions containing a partially purified extract of grass pollen. There are three different solutions each containing a specific weed pollen extract.

Soluprick SQ Weed Pollen *Parietaria judaica* is used in the diagnosis of specific IgE mediated allergic diseases and may be used in adults and children.

Soluprick SQ Weed Pollen *Parietaria judaica* is for administration by the skin prick test only on the forearm or back of the patient.

PHARMACEUTICAL ASSESSMENT

REQUESTS FOR INSPECTION ACTION PRIOR TO AUTHORISATION

Manufacturing and batch release site: ALK-Abelló, S.A. Miguel Fleta 19, E 28037, Madrid, Spain

GMP authorisations dated 27/01/2003 and 03/05/2000 were provided for applications PL 10085/0016. ALK-Abelló S.A. was inspected by the Spanish authorities on 12 May 2005. The inspection concerned the Production Facilities Extension and the outcome of the inspection was given as positive.

The applicant has also provided a valid GMP certificate for ALK-Abello S.A at Miguel Fleta 19, Madrid. This company is registered with the Spanish Medicines Agency (No. 3.196-E) and authorised for manufacturing of medicines (small volume injectables and oral solutions) according to GMP. The certificate is dated 29 December 2004.

INTRODUCTION

LEGAL BASIS
These are simple abridged applications are submitted in accordance with Article 10c (informed consent application) in accordance with Directive 2001/83/EC as amended, as previously agreed with MHRA.

USE
Soluprick SQ Weed Pollens are aqueous solutions containing a partially purified extract of weed pollen. There are three different solutions each containing a specific weed pollen extract (listed under the Drug Substance Specifications section in this report).

Soluprick SQ Weed Pollens are intended for skin prick testing (SPT) in the diagnosis of specific IgE mediated allergic diseases.

The Pharmacotherapeutic group ATC code is V 04 CL: Tests for allergic diseases.
Pharmaceutical form and strength: Solution for skin prick test, 10 HEP

Route of administration: Epicutaneous use.

SCIENTIFIC ADVICE
None given.

LEGAL STATUS
On 28 October 2005 the marketing authorisations for Soluprick weed pollen kit (PL 10085/0016) were granted by MHRA. These kits contain the individual pollen extracts for skin prick testing. The current application is for individual license applications for each of the components of the pollen kits covered by PL 10085/0016.

The documentation consists of Module 1 and expert statements from quality, preclinical and clinical experts that the applications made is identical to the corresponding product authorised under PL 10085/0016.

The products are also authorised in the Czech Republic, Denmark, Finland, Germany, Iceland, The Netherlands, Poland, Slovac Republic, Sweden and Switzerland.

DRUG SUBSTANCE

GENERAL INFORMATION

Soluprick SQ Weed Pollens are aqueous solutions of containing a partially purified extract of weed pollen. There are three different solutions each containing a specific weed pollen extract, as follows:
Soluprick SQ Mugwort (*Artemisia vulagaris*), PL 10085/0033
Soluprick SQ Pellitory of the Wall (*Parietaria judaica*), PL 10085/0028
Soluprick SQ Upright Pellitory (*Parietaria officinalis*), PL 10085/0029

Soluprick SQ Weed Pollens are intended for skin prick testing (SPT) in the diagnosis of specific IgE mediated allergic diseases.

The active ingredient is standardised with respect to the content of major allergens and the biological activity is controlled by a total potency assay. The potency is expressed as HEP (histamine equivalent in prick testing).

MANUFACTURE

Manufacturing of Soluprick is performed in ALK-Abelló S.A. in Madrid.

CHARACTERISATION

Not applicable.

CONTROL OF DRUG SUBSTANCE

Drug Substance Specifications
The specifications of the following drug substances (pollens) have been submitted and are acceptable.

- *Artemisia vulagaris*
- *Parietaria judaica*
- *Parietaria officinalis*

Suitability of the BP/Ph Eur Monograph
Pollen requirements are based on current NfG on Allergen Products (CPMP/BWP/243/96) and Ph. Eur. monograph, Allergen Products 01/2005:1063.

REFERENCE STANDARDS OR MATERIALS

No change.

CONTAINER CLOSURE SYSTEM
No change.

STABILITY
The applicant has provided data to support the 5 year shelf life at -20º ± 5ºC for the weed pollens. This shelf life can be accepted.

Drug Product

DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT
The Drug Product in these simple abridged applications has the same qualitative and quantitative composition in terms of active substances, excipients and the same pharmaceutical form as the currently approved Soluprick kit (PL 10085/0016).

The drug product is a phosphate-buffered, glycerol-containing solution of weed pollen extracts, preserved with phenol, intended for diagnosis of tree pollen allergy by skin prick test (SPT).

Each preparation is presented in a multi-dose container consisting of a clear, hydrolytic Type I glass bottle closed with a halobutyl rubber stopper and a white polypropylene screw cap. The device for administration is supplied separately, and consists of either a pipette applicator or dropper applicator complying with Dir 93/42/EEC on Medical Devices.

Each bottle contains 2 ml of solution

INGREDIENT	**Function**	**Ref Standard**
Drug Substance		
Allergen Extract		In-House Reference
Artemisia vulgaris		
Parietaria judaica		
Parietaria officinalis		
Excipients		
Sodium chloride	Isotonicity	Ph. Eur.
Phenol	Preservative	Ph. Eur.
Glycerol	Stabiliser/Viscosity	Ph. Eur.
Disodium phosphate $2H_2O$	pH buffer	Ph. Eur.
Sodium dihydrogen phosphate $2H_2O$	pH buffer	Ph. Eur.
Sodium hydroxide &/ hydrochloric acid	pH adjustment	Ph. Eur.
Water for injections (in bulk)	Solvent	Ph. Eur.

PHARMACEUTICAL DEVELOPMENT
No change.

MANUFACTURE
Flowcharts have been provided for summary of manufacturing processes for weed pollens. No changes have been made to the manufacturing process.

CONTROL OF EXCIPIENTS
No change.

CONTROL OF DRUG PRODUCT
The drug product specification has been set in accordance Ph. Eur. monograph and the EU NfG on Allergen Products. Tests described in the monograph are sterility, protein profile, total allergenic activity and determination of individual allergens.

The drug product specifications of the following skin prick test diagnostics have been submitted and are satisfactory:

Weed pollens
- *Artemisia vulagaris*
- *Parietaria judaica*
- *Parietaria officinalis*

The drug product specifications for the above pollens have been submitted and are acceptable.

As indicated in the specifications, the recommended storage conditions for the drug product are 2ºC-8ºC and the proposed expiry date is 3 years from the date of analysis.

REFERENCE STANDARDS OR MATERIALS
No change.

CONTAINER CLOSURE SYSTEM
Each preparation presented in a multi-dose container consisting of a clear, hydrolytic Type I glass bottle closed with a halobutyl rubber stopper and a white polypropylene screw cap. Each package contains one vial with 2ml solution for skin prick test. The device for administration is supplied separately, and consists of either a pipette applicator or dropper applicator complying with Dir 93/42/EEC on Medical Devices.

STABILITY
No change.
The proposed shelf life is 36 months with an in-use shelf life of 6 months after first opening the vial without exceeding the expiry date when stored at 2°-8°C with periodic excursions to 25°C ± 2°C when in use. The proposed shelf life and storage conditions are accepted.

BIOEQUIVALENCE / BIOAVAILABILITY
Not applicable.

ESSENTIAL SIMILARITY
Not applicable

APPENDICES

FACILITIES AND EQUIPMENT
No change

ADVENTITIOUS AGENTS SAFETY EVALUATION
Not applicable

NOVEL EXCIPIENTS
Not applicable

REGIONAL INFORMATION

PROCESS VALIDATION SCHEME FOR THE DRUG PRODUCT
Not applicable.

MEDICAL DEVICE ISSUES
Dropper applicator and pipette applicator are CE marked in compliance with Dir 93/42/EEC, certificates provided for original applications PL 10085/0016.

TSE ISSUES
The glycerol is certified of non-animal origin in original applications. No other TSE issues identified.

ASSESSOR'S COMMENTS ON Module I

NAME AND APPEARANCE (IF APPLICABLE)

SPC

Satisfactory.

PATIENT INFORMATION LEAFLET

LABEL
These have been agreed with the applicant.

APPLICATION FORM

Assessor's Overall Conclusions
These new National product applications are to allow the Company to market the individual components of the Soluprick SQ Weed Pollens, which are currently licensed as kits for skin prick testing (SPT). This current series of applications covers three weed pollens. The products are partially purified extracts of weed pollens in a 50% solution of glycerol, intended for use in the diagnosis of specific IgE-mediated allergic diseases. This application for Soluprick SQ Weed pollen *Parietaria judaica* is approvable.

Date: 21 November 2006

CLINICAL ASSESSMENT

INTRODUCTION

TYPE OF APPLICATION AND REGULATORY BACKGROUND
This is a national marketing authorisation application.
This application is submitted in accordance with the Article 10c, informed consent application, in Directive 2001/83/EC.

CLINICAL BACKGROUND
On 28 October 2005 the marketing authorisations for Soluprick Weed pollen kit (PL 10085/0016) was granted by the MHRA. Each pollen kits consist of individual vials of pollen.

ALK Abelló is applying for three abridged applications to launch vials of the individual weed pollens. These three abridged applications are submitted in accordance with article 10c (informed consent application) in accordance with directive 2001/83C.

As per applicant the drug product possesses the same qualitative and quantitative composition in terms of active substances, excipients and the same pharmaceutical form as the Soluprick kit.

The individually packed vials are supported by the already submitted quality, non-clinical and the clinical documentation. As per applicant the products are in relation to quality, non-clinic and clinic documentation identical to the corresponding product authorised under PL 10085/0016. The Marketing Authorisation holder is the same.

INDICATIONS
Soluprick SQ Weed Pollens are used in the diagnosis of specific IgE mediated allergic diseases.

DOSE AND DOSE REGIMEN
Soluprick SQ Weed Pollens 10 HEP are recommended as the optimal biological potency of the allergen when taking into account the meaning of high sensitivity related to high specificity. The potency is expressed in HEP (Histamine Equivalent in Prick testing) which is related to the allergenic activity of the allergen product in the skin of the allergic patient.

ALK Positive control (histamine dihydrochloride 10 mg/ml) is used as reference and ALK Negative control (Saline solution) is used to evaluate unspecific reactions.

When performing SPT the amount of solution introduced into the superficial layer of the skin is extremely low, approximately 3 x 10-3 µl (S. Dreborg, Allergy no. 10, Vol 44, 1989).

GCP ASPECTS
NA

ORPHAN MEDICINAL PRODUCTS
NA

PAEDIATRIC DEVELOPMENT PROGRAMME
NA

SCIENTIFIC ADVICE
Not given.

LEGAL STATUS
On 28 October 2005 the marketing authorisations for Soluprick weed pollen kit (PL 10085/0016) was granted by the MHRA. Each pollen kits consist of individual vials of pollen.

ALK Abelló is applying for three abridged applications to launch vials of the individual pollens. These three abridged applications are submitted in accordance with article 10c (informed consent application) in accordance with directive 2001/83C.

As per applicant the drug product possesses the same qualitative and quantitative composition in terms of active substances, excipients and the same pharmaceutical form as the Soluprick kit.

The individually packed vials are supported by the already submitted quality, non-clinical and the clinical documentation. As per applicant the product is in relation to quality, non-clinic and clinic documentation identical to the corresponding product authorised under PL 10085/0016. The Marketing Authorisation holder is the same.

CLINICAL PHARMACOLOGY
NA

CLINICAL EFFICACY
The applicant has not enclosed any new data. The individually packed vials are supported by the already submitted quality, non-clinical and the clinical documentation. As per applicant the product is in relation to quality, non-clinic and clinic documentation identical to the corresponding product authorised under PL 10085/0016.

ASSESSORS' OVERALL CONCLUSIONS ON CLINICAL EFFICACY
No new data has been enclosed.

CLINICAL SAFETY
The applicant has not enclosed any new data and as per applicant the clinical documentation is identical to the corresponding product authorised under PL 1085/0016.

ASSESSOR'S OVERALL CONCLUSIONS ON CLINICAL SAFETY
No new data has been enclosed.

EXPERT REPORTS

Clinical expert report is written by Medical Doctor Ea Dige, Head of Pharmacovigilance in ALK-Abelló, Hørsholm Denmark.

PRODUCT LITERATURE

Not enclosed

SPC

PATIENT INFORMATION LEAFLET

LABEL

APPLICATION FORM

OVERALL CONCLUSION

PHARMACOKINETICS
NA

PHARMACODYNAMICS
NA

EFFICACY
No new data has been enclosed. As per applicant the drug product possesses the same qualitative and quantitative composition in terms of active substances, excipients and the same pharmaceutical form as the Soluprick kit.

The individually packed vials are supported by the already submitted quality, non-clinical and the clinical documentation. As per applicant the product is in relation to quality, non-clinic and clinic documentation identical to the corresponding product authorised under PL 10085/0016.

SAFETY
No new data has been enclosed. As per applicant the drug product possesses the same qualitative and quantitative composition in terms of active substances, excipients and the same pharmaceutical form as the Soluprick kit.

The individually packed vials are supported by the already submitted quality, non-clinical and the clinical documentation. As per applicant the product is in relation to quality, non-clinic and clinic documentation identical to the corresponding product authorised under PL 10085/0016.

RISK BENEFIT
Benefit risk remains positive as no new data is demonstrated. The marketing authorisation for Soluprick Weed pollen kit (PL 10085/0016) was granted by the MHRA. As per applicant in this submitted abridged application for Soluprick SQ Weed Pollen

Parietaria judaica, the products are in relation to quality, non-clinic and clinic documentation identical to the corresponding product authorised under PL 10085/0016.

RECOMMENDED CONDITIONS FOR MARKETING AUTHORISATION
None

28th November, 2006
MHRA

PRE-CLINICAL ASSESSMENT

No pre clinical assessment was performed nor was any required for an application of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of Soluprick SQ Weed Pollen *Parietaria judaica* 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

Soluprick SQ Weed Pollen *Parietaria judaica* 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 labelling are satisfactory.

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 Soluprick SQ Weed Pollen *Parietaria judaica*. The risk benefit is therefore considered to be positive.

SOLUPRICK SQ WEED POLLEN *PARIETARIA JUDAICA* (PELLITORY OF THE WALL) 10 HEP SOLUTION FOR SKIN PRICK TEST 2ML PER VIAL

(Parietaria judaica)

PL 10085/0028

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the marketing authorisation application on 16th January 2006.

2 Following assessment, a request for supplementary information was sent to the applicant on the 21st November 2006.

3 The applicant submitted its responses to supplementary information request in a letter dated 25th January 2007.

4 The MHRA completed its assessment of the application on 25th May 2007.

5 The application was determined on 12th July 2007. .

SOLUPRICK SQ WEED POLLEN *PARIETARIA JUDAICA* (PELLITORY OF THE WALL) 10 HEP SOLUTION FOR SKIN PRICK TEST 2ML PER VIAL

(Parietaria judaica)

PL 10085/0028

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Soluprick SQ Weed Pollen *Parietaria judaica* (Pellitory of the Wall), 10 HEP, Solution for skin prick test, 2 ml per vial

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Soluprick SQ Weed Pollens is a glycerinated preparation containing standardised allergen extracts dissolved in equal parts of buffered saline and sterile glycerol.

Active ingredients:
The active ingredient is a partly purified pollen allergen extract which contains the relevant allergen. The Soluprick SQ Weed Pollen species are shown above. The active ingredient is standardised with respect to the content of major allergen and the biological activity is controlled by a total potency assay. The potency is expressed in HEP (Histamine Equivalent in Prick testing). The biological activity of Soluprick SQ Weed Pollen is related to the reaction in the skin of an allergic patient measured relative to a histamine dihydrochloride solution.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for a skin prick test (SPT)

4 CLINICAL PARTICULARS

THERAPEUTIC INDICATIONS

Soluprick SQ Weed Pollen is used in the diagnosis of specific IgE mediated allergic diseases.

4.2 Posology and method of administration

Dosage:
Soluprick SQ Weed Pollen 10 HEP is recommended as the optimal biological potency of the allergen when taking into account the meaning of high sensitivity related to high specificity. The potency is expressed in HEP (Histamine Equivalent in Prick testing) which is related to the allergenic activity of the allergen product in the skin of the allergic patient.

ALK Positive control (histamine dihydrochloride 10 mg/ml) is used as reference and ALK Negative control (Saline solution) is used to evaluate unspecific reactions.

When performing a SPT the amount of solution introduced into the superficial layer of the skin is extremely low, approximately 3 x 10^{-3} µl. (S. Dreborg, Allergy no. 10, Vol 44, 1989)

Skin prick test technique

- The SPT is preferably performed on the volar side of the forearm. Alternatively the test can be performed on the back of the patient.

- The skin must be dry and clean and may be disinfected with 70% alcohol.

- Each test preparation and the controls are applied in droplets on the skin in an appropriate distance from each other (a numbered tape can be used).

- The superficial layer of the skin is pierced with an ALK Lancet perpendicular to the skin through the droplet. Hold it for 1 second and draw back the lancet. For each test preparation and control a new sterile, disposable ALK Lancet is used. The positive control is applied last.

- The droplets are wiped off with a tissue. Do not mix the preparations by sweeping!

- Start to read the reaction of the preparations after 15 minutes beginning with the positive control. A positive reaction is a pale weal (oedema) with a red flare (erythema). To record the weal in the patient's report: mark the contour of the weal with a pen, stick transparent tape over the weal. Press and transfer the tape to the report. The flare can be recorded likewise.

Size of the weal

The mean weal diameter of the allergen product ($D_{a)}$ and of the histamine control (D_h) is calculated as $D = (D_l + d_p)/2$, where D_l is the longest diameter and d_p is the diameter mid-ortogonal to D_l.

Interpretation of results

- Reactions of the allergen product can be graded in relation to the histamine control reaction. This relation is called the skin index (SI).

$$\mathbf{SI = D_a/D_h}$$

0	: negative reaction
+	: $SI \leq 0.5$
++	: $0.5 < SI \leq 1.0$
+++	: $1.0 < SI \leq 2.0$
++++	: $2.0 < SI$

- By use of a biological standardised allergen product a mean weal diameter $\geq$ 3 mm indicates that the patient is sensitized to the respective allergen source.

4.3 Contraindications

In extremely rare cases allergic reactions may occur and therefore, a SPT should be avoided when patients are treated with beta-blockers. Recovery from an anaphylactic reaction through the action of adrenaline may be hindered by beta-blockers since these drugs might influence an effective anti-anaphylactic treatment. Therapy with beta-blockers has to be considered an absolute contra-indication.

4.4 Special warnings and precautions for use

Any diseases seriously affecting the patient's general condition; skin lesions in the area used for the testing; dermatographism; dermatitis. Atopic eczema may hamper the reliability of the test.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant treatment with antiallergic symptomatics may affect the result of the test.

It is recommended that patients who are going to have a skin prick test performed discontinue treatment with:

Therapeutic agent	Interval between last given dose and the SPT
Short-acting antihistamines	2-3 days
Long-acting antihistamines	8 weeks
Hydroxyzine	2 weeks
Ketotifen	2 weeks
Tricyclic antidepressants	2 weeks
Local application of potent steroid ointment	2-3 weeks

Corticosteroids in doses lower than 30 mg of prednisone/prednisolone per day for up to one week do not reduce the response to skin tests.

Oral low dose glucocorticoids (doses less than 10 mg of prednisolone per day) need not to be discontinued prior to skin testing.

4.6 Pregnancy and lactation

Pregnancy is not an absolute contraindication for skin testing. Skin prick testing with Soluprick may be performed during lactation.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Undesirable effects occurring are related to the fact allergenic material is applied. The local reaction is an integrated part of the diagnosis, and the following type of reactions related directly to the patient's allergy might occur.

Local reactions
The weal is continuously spreading and pseudopodia may be formed during the first 15-20 minutes after application. Note that in some cases a late reaction (6-24 hours after) may occur after application of the allergen in the form of a diffuse swelling.

Systemic reaction
In rare cases a general reaction may develop which can be treated with relevant symptomatics.

Anaphylactic reaction
Although never reported a theoretical possibility exists of development of an anaphylactic reaction after a few seconds or minutes. For this reason an emergency kit with a ready for use adrenaline syringe must always be available.

4.9 Overdose

Not relevant

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Soluprick SQ Weed Pollen is used for specific diagnosis by skin prick testing. The preparation is mixtures of molecules with high molecular weight compounds.

The allergenic substance of the preparation can react with the immune system of an allergic patient provided IgE antibodies to the corresponding allergen are released. An immediate allergic reaction will occur within 10-20 minutes, characterised by a weal and flare.

This reaction is mainly caused by binding the allergen to specific IgE attached to mast cells, resulting in release of vaso-active agents like histamine. Some patients also develop a late phase reaction, i.e. a diffuse swelling and redness, starting 2 to 3 hours after the allergen piercing, peaking at 6-12 hours and disappearing within 12-24 hours.
Lymphocytes are involved in the late phase response; the exact mechanism has not yet been elucidated.

5.2 Pharmacokinetic properties

Neither the doses applied in a SPT - in terms of weight less than 0.1 µg - nor the route of administration indicate that Soluprick SQ Weed Pollen is used to acquire a clinical effect after systemic absorption.
No attempt has been made to account for the fate of the individual components.

5.3 Preclinical safety data

No toxicological studies have been performed. However, long term clinical experience confirms that non- allergic reactions are hardly of any significance.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Disodium phosphate, dihydrate
Sodium dihydrogen phosphate, dihydrate
Phenol
Sodium chloride
Glycerol
Water for Injections

The sodium content of Soluprick SQ Weed Pollen is less than 1 mmol sodium (23 mg) per dose; therefore it is essentially "sodium free"

6.2 Incompatibilities

None known. In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

Shelf life of medicinal product as packaged for sale: 3 years
Shelf life after opening the container: 6 months

6.4 Special precautions for storage

Store in a refrigerator at 2-8 °C
Do not freeze. Store in original packaging in order to protect from light.

6.5 Nature and contents of container

Vial (type I glass) with a halobutyl rubber stopper and a screw cap (polypropylene).

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

ALK-Abelló A/S
Bøge Allé 6-8
DK-2970 Hørsholm

Denmark

8 MARKETING AUTHORISATION NUMBER

PL 10085/28

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/07/2007

10 DATE OF REVISION OF THE TEXT

09/07/2007

Patient Information Leaflet

SOLUPRICK SQ WEED POLLEN *PARIETARIA JUDAICA* (PELLITORY OF THE WALL) 10 HEP SOLUTION FOR SKIN PRICK TEST 2ML PER VIAL

(Parietaria judaica)

PL 10085/0028

PATIENT INFORMATION LEAFLET

SOLUPRICK SQ 10 HEP
Solution for skin prick testing

Weed Pollen, Weed Pollen, Weed Pollen, Animal Hair and Dander and House Dust Mites

1. WHAT YOU SHOULD KNOW ABOUT SOLUPRICK SQ

Please read this leaflet carefully before you start treatment with Soluprick SQ. Soluprick SQ is a solution for skin prick testing (SPT). It is used in the diagnosis of specific allergenic diseases. If you have any questions or are in any doubt about anything, please ask your doctor or nurse.

2. WHAT IS THE SKIN PRICK TESTING FOR?

Soluprick SQ is used to check if you have an allergy to one of the following groups of allergens:

Grass pollen
Tree pollen
Weed pollen
Animal hair and dander
House dust mites

See section number 7

3. BEFORE YOU ARE GIVEN YOUR SKIN PRICK TEST

- Are you regularly taking Beta-blockers to control your blood pressure?
- Have you any skin problems in the area to be used for testing?
- Are you allergic to any of the ingredients in Soluprick SQ?
- Are you taking, antihistamines, hydroxyzine, ketotifen, tricyclic antidepressants or using steroid ointment?
- If the answer to any or all of the above questions is YES, TELL YOUR DOCTOR/NURSE BEFORE HE/SHE GIVES YOU SOLUPRICK SQ

4. HOW WILL YOU BE GIVEN THE SKIN PRICK TEST?

- The Skin Prick Test is usually carried out on the inner side of the forearm. Alternatively the test can be done on your back.
- Your skin must be dry and clean and may be disinfected with alcohol by the nurse or doctor
- Test preparations and the controls are applied in droplets on the skin at an appropriate distance from each other (a numbered tape may be used).
- The top layer of the skin is pierced by the doctor/nurse with an ALK lancet through the droplets.
- The reaction is read after 15 minutes. A positive reaction is a pale small raised swelling or weal with a red edge.

5. AFTER YOU HAVE BEEN GIVEN THE SKIN PRICK TEST

Normally a Skin Prick Test does not cause any problems but occasionally some people may get side effects such as:

- A continuously spreading weal may be formed at the site during the first 10-20 minutes after application of the allergen.
- Widespread swelling and redness may happen 6-24 hours after the application of the allergen.

If you experience any of these side effects, and they stay or become troublesome, tell your doctor or pharmacist.
If you get any other unusual or unexpected side effect, you should tell your doctor or pharmacist at once.

Anaphylactic reaction
In extremely rare cases an anaphylactic reaction (a severe reaction throughout the body that is recognised by difficulty in breathing, fainting, itching, and weals) may develop after a few seconds or minutes. For this reason an emergency kit with a 'ready for use' adrenalin syringe will always be available.

TELL YOUR DOCTOR/NURSE IMMEDIATELY IF YOU FEEL ANY OF THESE CHANGES. He or she will be able to give you the right treatment at once to make you feel well.

6. HOW SHOULD THE SKIN PRICK TEST BE STORED?

- The clinic/hospital will store the Skin Prick Test, solution.
- This medicine should be kept in a refrigerator (between 2ºC and 8ºC) out of the reach and sight of children, as the medicine could harm them.
- Do not freeze the solution.
- Keep the vials in the outer carton to protect it from light.
- Do not use the skin prick test solution after the expiry date, which is printed on the carton and label.

7. WHAT IS IN THE MEDICINE?

Soluprick SQ is a solution for skin prick testing that contains an extract of specific allergen. The allergen is the substance that causes the allergic disease. Soluprick SQ also contains the inactive ingredients, disodium phosphate, sodium dihydrogen phosphate, phenol, sodium chloride, glycerol and water for injections.

The following individual allergens are available:

Grass pollen: Meadow Foxtail, Cock's Foot, Meadow Fescue, Perennial Ryegrass, Timothy Grass, Kentucky Blue Grass, Cultivated Rye.
Tree pollen: European Alder, Grey Alder, Silver Birch, Hazel
Weed pollen: Mugwort, Pellitory of the Wall, Upright Pellitory.
Animal hair and dander: Horse Dander, Dog Hair, Cat Hair
House dust mites: Dermatophagoides farinae, Dermatophagoides pteronyssinus

Each single allergen is provided in a 2 ml glass vial.

The strength of the products is 10 HEP

The biological activity of Soluprick SQ is related to the reaction in the skin of an allergic patient measured relative to a histamine dihydrochloride solution.

8. MANUFACTURER AND PRODUCT LICENCE HOLDER

Product Licence Holder:
ALK-Abelló A/S
Bøge Allé 6-8
DK-2970 Hørsholm
Denmark

Manufacturer:
ALK-Abelló S.A.
Miguel Fleta 19
E-28037 Madrid
Spain

9. DISTRIBUTOR

ALK-Abelló Ltd.
1 Tealgate
Hungerford
Berkshire RG17 OYT
United Kingdom
Tel: 01488 686 016

10. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

June 2007

11. FURTHER INFORMATION

Allergy UK
Tel: 01322 619 898
www.allergyuk.org

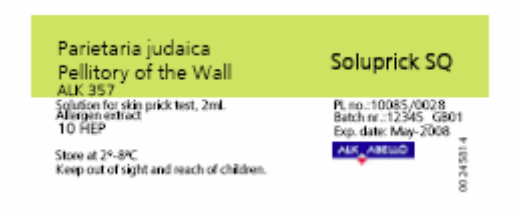
Labelling

SOLUPRICK SQ WEED POLLEN *PARIETARIA JUDAICA* (PELLITORY OF THE WALL) 10 HEP SOLUTION FOR SKIN PRICK TEST 2ML PER VIAL

(Parietaria judaica)

PL 10085/0028

VIAL


Parietaria judaica
Pellitory of the Wall
ALK 357
Solution for skin prick test, 2ml.
Allergen extract
10 HEP
Store at 2°-8°C
Keep out of sight and reach of children.
Soluprick SQ
PL no.:10085/0028
Batch nr.:12345_GB01
Exp. date: May-2008
ALK-ABELLÓ
00 245814

BOX


Solution for skin prick test, 2ml.
Allergen extract
10 HEP
Excipients:
Disodium phosphate dihydrate 5.96 mg, Sodium dihydrogen phosphate dihydrate 5.2 mg, Phenol 5.1 mg, Sodium chloride 5.0 mg, Glycerol 0.5 ml, Water for injection q.s. to 1ml.
Store in a refrigerator at 2°C-8°C. Do not freeze.
Store in the original packaging in order to protect from light
In-use shelf-life: 6 months.
Keep out of sight and reach of children
POM
Solution for skin prick test, 2ml.
Allergen extract
10 HEP
Soluprick SQ
Parietaria judaica
Pellitory of the Wall
ALK 357
00 245815
PL no.:10085/0028
Batch nr.: 12345_GB01
Exp. date: May-2008
Solution for skin prick test, 2ml.
Soluprick SQ
Parietaria judaica
Pellitory of the Wall
ALK 357
10 HEP
ALK-ABELLÓ
Manufacturer
Miguel Fleta, 19 Madrid
ES-28037 Spain
M.A.holder ALK-ABELLO A/S
Bøge Allé 6-8
DK-2970 Hørsholm Denmark