SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Merck skin testing solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active constituents	Specification ref
FORMULATION 1	
Pollens	
Grasses	
Grass Mix (Cocksfoot, Meadow grass, Rye grass, Tall fescue, Timothy, HSE Yorkshire fog)	HSE
Barley	
Maize	HSE
Oat (cult)	HSE
Rye	HSE
Wheat	HSE
Weeds	
Weed mix (dandelion, mugwort, nettle, pellitory , plantain	HSE
Dandelion	HSE
Mugwort	HSE
Nettle	HSE
Plantain	HSE
Pellitory	HSE
Trees	
Tree mix (early blossoming :alder, elm, hazel, poplar, willow)	HSE
Tree mix (mid - blossoming: beech birch, oak, plane)	HSE
Alder	HSE
Ash	HSE
Beech	HSE
Birch	HSE
Elder	HSE
Elm	HSE
False Acacia	HSE
Hazel	HSE
Oak	HSE
Plane	HSE
Poplar	HSE
Sycamore	HSE
Willow	HSE

Flowers

Flower mix (Aster, chrysanthemum, dahlia, golden rod , marguerite daisy	HSE
Aster	HSE
Chrysanthemum	HSE
Dahlia	HSE
Golden rod	HSE
Marguerite daisy	HSE

Moulds

Alternaria	HSE
Aspergillus	HSE
Cladosporium	HSE
Penicillin	HSE

Epithelia

Feather mix (duck, goose, chicken)	HSE
Budgerigar	HSE
Cat	HSE
Cow	HSE
Dog	HSE
Golden Hamster	HSE
Guinea Pig	HSE
Horse	HSE

Other inhalants

Dermatophagoides Pteronyssus	HSE
Dermatophagoides Farinaen (house dust mites)	HSE
Rye flour	HSE
Wheat flour	HSE

Skin prick test solutions for:

FORMULATION 2	
(Histamine) positive control	Quantity/Dose
(Histamine 1 - 999)	
Histamine dihydrochioride	1.7mg/ml
FORMULATION 3	
(Glycero-saline) negative control	
No actives stated.	

3 PHARMACEUTICAL FORM

Aqueous Allergen Extract.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Merck skin testing solutions are used for the diagnosis of IgE - mediated diseases (type I in the classification of Coombs and Gell) by the prick test.

4.2 Posology and method of administration

Route of administration:
Prick testing only.

1. The test area is the volar surface of the lower arm. The arm is relaxed and supported on a table.

2. Particular preparation of the skin is unnecessary. When outdoor temperatures are extreme a brief acclimatisation should be allowed. If the skin is cleaned with water, ethanol etc. Wait for at least another 2 minutes in order to allow blood circulation of the skin to normalise.

3. One drop of each test solution is dropped onto the marked skin area using a pipette. Distance between drops should be CA. 4 cm.

4. The skin is pierced obliquely through the drops and slightly raised with a prickling needle or a lancet, so that a small amount of the test solution can enter the skin under the tip of the needle (modified prick test). Avoid bleeding.

5. Between the single tests the pricking needle or the lancet does not have to be changed for a single person: it only has to be cleaned with a sterile swab between each test in order to avoid allergen transfer.

6. At the beginning or at the end of a test series two control tests have to be performed in order to determine the patient's individual skin reaction.

A) Negative control test with physiological saline (solvent)
B) Positive control test with histamine solution (1+999)

7. Remaining test liquid on the skin should be removed only after 5 to 10 minutes in case of a normal test reaction: it must be removed immediately if a severe reaction is observed.

8. Final results are read after 20 minutes. The course of the reaction however, must be followed by repeated observation.

9. A positive test reaction is a pale yellow wheal surrounded by a red flare (erythema). Size of wheal and erythema of histamine solution are used as reference and stronger test reactions are recorded as ++++, weaker ones as + or ++. The negative solvent reaction is documented with ϕ.

10. Allergen mixtures only serve to do orientating tests: in case of positive test reaction the single allergens must be tested one by one. (The single allergens of the grass - and the grass/cereals-mixture are not further tested).

4.3 Contraindications

Diseases severely affecting the general status of health , pathological changes of skin around the test area. During pregnancy and beta- blockers therapy skin tests should be avoided where possible.

Depending on the constitution prick testing may be practised as early as from one year of age on.
Generally, however this test is undertaken from four to five years on.
As adrenaline is recommended for treatment of allergic side reactions. The contra-indications
for adrenaline must be observed.

4.4 Special warnings and precautions for use

The urgent and life -saving measure is the extremely careful and very slow intravenous injection of adrenaline (epmephrine), which must be given (with immediate volume substitution) before all other measures. The dose must be adjusted to the clinical situation.

After testing the patient must be kept under medical observation for at least 30 min, after which time a medical assessment is made. In extremely rare cases side reactions may occur even a few hours after testing. When in doubt, especially after the appearance of systemic reactions ,the patients should inform his doctor immediately.

For the treatment of anaphylactic reactions reference is made to the guidelines "emergency therapy of anaphylaxis" the medical approach varies on the basis of individuals requirements.

Antihistamines, corticosteroids and drugs with an accompanying antihistaminic effect may cause false negative results. If possible these drugs should not be applied for at least 48 hours before skin testing (astemizole, 6-8 weeks).

4.5 Interaction with other medicinal products and other forms of interaction

Antihistamines , corticosteroids and drugs with an accompanying antihistaminic effect may cause false negative results. If possible these drugs should not be applied for at least 48 hours before skin testing (astemizole, 6-8 weeks).

4.6 Pregnancy and lactation

During pregnancy skin test should be avoided where possible.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Allergic side-effects occur very rarely. Highly sensitised patients may suffer from stronger local reactions.

In extremely rare cases generalised side reactions and even severe systemic reaction (anaphylactic shock) may occur. Therefore an emergency -kit with a ready for use adrenaline syringe for immediate use must be available whenever testing is done. Anaphylactic shock can develop a few seconds to several minutes after the Allergen -testing often before a local reaction has appeared. The typical alarm syndrome consist s of burning, itching ,and a

sensation of heat under the tongue, in the throat , and especially on the palms of the hands and soles of feet.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The extract of the specific allergen, when administered by prick test, will provoke a Type I
hypersensitivity reaction in those subjects sensitised to that particular allergen. It is used as a diagnostic test.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Other constituents	Specification Ref	mod		Quantity /dose	Unit
FORMULATION 1					
Sodium chloride	DAB	10		9	mg/ml
Phenol	DAB	10		2	mg/ml
Glycerol	DAB	10		563	mg/ml
Water for injection 499mg	DAB	10	TO	1	ml
FORMULATION 2					
(Histamine) positive control					
Sodium chloride	DAB	10		9	mg/ml
Phenol	DAB	10		2	mg/ml
Glycerol	DAB	10		563	mg/ml
Water for injection 499mg	DAB	10	TO	1	ml
FORMULATION 3					
(Glycero-saline) Negative control					
Sodium chloride	DAB	10		9	mg/ml
Phenol	DAB	10		2	mg/ml
Glycerol	DAB	10		563	mg/ml
Water for injection 499mg	DAB	10	TO	1	ml

6.2 Incompatibilities

None stated

6.3 Shelf life

36 months (Shelf life for skin prick test solutions containing the allergens).
36 months (Shelf life for skin prick test solutions containing positive and negative control - Control solutions)

6.4 Special precautions for storage

The preparation must be stored in a refrigerator at temperatures between 12°C and 18°C Do not freeze. The expiry date specified on the pack and on each vial must be observed ! After the expiry-date has been exceeded the drug should no longer be used.
Keep all drugs out of children's reach.

6.5 Nature and contents of container

Glass bottles with droppers.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

Allergopharma Joachim Canzer KG
Hermann Komer Strasse 52
D-2 1465 Reinbek
Germany

8 MARKETING AUTHORISATION NUMBER(S)

PL 04921/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01 June 1999

10 DATE OF REVISION OF THE TEXT

19/02/2009