

MITES

Individual allergen extracts

Extracts in IR/mL

Dermatophagoides pteronyssinus, Dermatophagoides farinae, Blomia tropicalis

ANIMAL ALLERGENS

Individual allergen extracts

Extracts in IR/mL

Cat

3. PHARMACEUTICAL FORM

Solution for skin-prick test

Product description: Colourless to off-yellow solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.

Evidence of type I allergy according to Gell and Coombs classification, presenting mainly rhinitis, conjunctivitis, rhino-conjunctivitis or asthma (mild to moderate) of a seasonal or perennial nature with the use of skin prick tests.

4.2 Posology and method of administration

Principle

The Skin Prick-Test consists in applying a drop of allergen extract solution on the skin and pricking the skin through the drop with an adequate medical device (lancet such as Stallerpoint®).

Method of administration

Skin-prick testing should be performed by trained personnel only.

The Skin Prick-Tests are preferably performed on the anterior face of the forearm. Alternatively the test can be performed on the back.

The skin of the tested zone is cleaned, disinfected with alcohol and dried.

- Apply one drop of each solution of allergen extract on the skin, in an appropriate distance from each other (approximately 3 cm).

- Take a lancet, between thumb and forefinger, and prick perpendicular to the skin through one drop applying a light rotation. Skin compression from 2 to 5 mm should be visible. Use a new sterile disposable lancet for each solution.

- Wipe off the drops without mixing the solutions, which could cause false positive results.

- It is preferable to mark out with a pen, the nature of the tested solutions.

Adequate skin reactivity is confirmed with ALYOSTAL Positive and Negative Controls (skin ability to react to histamine and lack of dermographism).

It is recommended to duplicate testing to detect new sensitizations and when changes in symptoms have occurred.

Results reading

The skin reaction usually occurs within 20 minutes following the tests; a positive reaction corresponds to the appearance of wheal (edema) with or without flare (erythema).

Read the results and trace margins (wheal, flare).

Record the extent of patient's reaction (defined by the edge of the edema and redness) electronically or with sticky tape (printing of edge of reaction). Record this information to patient's report.

Interpretation of the results

The reactivity is evaluated by comparison of the wheal and flare due to the tested allergen solutions with the controls.

The test is positive when the wheal has a diameter wider than 3 mm or if it is 3 mm wider than the negative control. Skin Prick-Test results can only be interpreted if reactions to positive and negative controls are those expected.

The occurrence of an early and transitory flare should be disregarded.

The patient must be kept under medical control for at least 30 minutes after the skin prick testing.

4.3 Contraindications

Hypersensitivity to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

As systemic allergic reactions (that could be life threatening when very severe) might occur, Skin Prick-Tests must be performed and interpreted in the presence or by a physician with experience in skin prick testing and in conditions allowing immediate emergency treatment if necessary (including epinephrine).

In case of occurrence of symptoms following skin prick testing such as intensive itching in palms of hands and soles of the feet, urticaria, mouth oedema, pharyngeal oedema leading to difficulty in swallowing, in breathing or voice modification, nausea, vomiting, a physician has to be consulted immediately.

Skin prick testing may not be the preferred diagnostic approach for patients who are taking medications that can adversely affect the efficacy of epinephrine (beta-adrenergic blocking agent, angiotensin-converting enzyme (ACE) inhibitors, tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs), see section 4.5).

Skin Prick Tests should be performed in patients in healthy condition.

In case of a fever or of a recent asthma attack that is confirmed clinically and/or by expiratory peak flow measurement, Skin Prick-Tests should not be performed before improvement and advice of the physician experienced in skin prick testing.

Skin Prick Tests must not be performed during an acute phase of the allergic disease.

Skin Prick test must be performed on healthy skin. Skin lesions (urticaria, atopic dermatitis, eczema, psoriasis) or dermatographism that may hamper the reliability of the test or exacerbate any pre-existing dermatosis must be carefully evaluated before the performance of the Skin Prick Tests.

In case of axillary lymph nodes clearing, it is preferable to realize the skin tests on the opposite forearm.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs can suppress skin tests, therefore it is always necessary to ask patients about medications they have taken in the preceding days (see table below). This is particularly true for oral H1-antihistamines, but also for other drugs which are not necessarily used for the treatment of allergic disease such as anxiolytics. Topical skin corticoids may alter skin reactivity.

Inhibitor effect of various treatments on skin prick test

Treatment	Intensity of the SPT suppression	Duration of the inhibitory effect of treatment after its termination	Expected impact on the wheal size
Oral H1-antihistamine	++++	2-7 days	Yes
Intranasal H1-antihistamine H2-antihistamine	0 to +		None None
Imipramines	++++	Up to 21 days	Yes
Phenothiazines	+ to ++	Up to 10 days	Yes
Corticosteroids Systemic - short term Systemic – long term Inhaled Topical skin	0 possible 0 + to ++	Up to 7 days	None None None Yes
Dopamine	+		None
Clonidine	++		None
Montelukast	0		None
Specific immunotherapy	0 to ++		None
UV light treatment systemic depending on light source, most intensive with PUVA	+++	Up to 4 weeks	Yes

In case of severe allergic reactions, use of epinephrine may be necessary.

Beta-blockers interact with epinephrine and the use of beta-blocker is therefore preventing the treatment of possible anaphylactic reactions. This risk would have to be considered prior to performing Prick-testing (see section 4.4).

The use of angiotensin-converting enzyme (ACE) inhibitors results in the relaxation of blood vessels. In case of anaphylaxis, serious hypotension could occur. Therefore, ACE inhibitor discontinuation or an alternative to ACE inhibitors should be considered for patients receiving Alyostal prick.

In patients treated with tricyclic antidepressants or mono amine oxidase inhibitors (MAOIs) risk of undesirable effects of epinephrine can be increased with possible fatal consequences. This risk would have to be considered prior to performing Prick-testing. (see section 4.4)

4.6 Fertility, pregnancy and lactation

Pregnancy

No clinical data are available for the use of Alyostal Prick in pregnant women. No adverse data on the clinical experience for the use of Alyostal Prick in pregnant women have been reported. No animal reproduction and development studies were conducted with Alyostal Prick. Allergen skin testing is generally not performed during pregnancy, because they may expose the pregnant woman to a risk of systemic allergic reaction.

Breast-feeding

No clinical data are available for the use of skin prick test during lactation. Skin prick-testing may be performed during lactation.

Fertility

No fertility studies were conducted with Alyostal Prick. However, histopathological examination of the male and female reproductive organs in a repeat-dose toxicity study with mite extract contained in Alyostal Prick revealed no adverse findings.

4.7 Effects on ability to drive and use machines

Alyostal Prick, skin prick test, has no influence on the ability to drive and use machines.

4.8 Undesirable effects

During diagnosis with Alyostal Prick, patients are exposed to allergens that may cause local and/or systemic allergic symptoms.

Allergic reactions including anaphylactic reactions (i.e: acute onset of an illness with involvement of the skin, mucosal tissue, or both, respiratory compromise, persistent gastrointestinal symptoms, or reduced blood pressure and/or associated symptoms) have been reported. Inform patients of the associated signs and symptoms and have them seek immediate care should these occur. Alyostal Prick should only be resumed at the instruction of a physician.

Tolerance in a patient may vary over time depending on the patient's condition and the environment.

The following table of adverse reactions is based on data from solicited reporting in clinical studies with frequency as follows: uncommon ($\geq 1/1,000$ to $<1/100$)

System Organ Class	Frequency	Adverse Drug Reactions
Skin and subcutaneous tissue disorders	Uncommon	Pruritus

Additionally, the following adverse reactions have been spontaneously reported during post marketing experience with unknown frequency:

- Local reactions: pain, edema, erythema, urticaria
- Systemic allergic reactions: anaphylactic reaction

The safety profile in the paediatric population is similar to that of adults.

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 national reporting system at the following address:

Státní ústav pro kontrolu léčiv
Šrobárova 48
100 41 Praha 10
Webové stránky: www.sukl.cz/nahlasit-nezadouci-ucinek

4.9 Overdose

Not relevant

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Tests for allergic disease
ATC code: V04CL

Mechanism of action and pharmacodynamic effects:

Positive skin test is indicative of the existence of antibodies specific for allergens to which the subject is sensitized.

Local reaction associated with edema, erythema and pruritus (Triad of Lewis) is the consequence of the *in situ* release of allergic mediators (Histamine, PAF-acether, ECFA, cytokines ...) triggered by the antigen-antibody reaction.

5.2 Pharmacokinetic properties

No pharmacokinetic studies were conducted.

5.3 Preclinical safety data

The genotoxicity and repeat dose toxicity studies which were conducted with some allergen extracts containing in Alyostal Prick revealed no special hazard for humans.

Chronic subcutaneous administration (26 weeks) of high dose levels of mite extracts (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*) to rats showed only local inflammatory reactions at the injection site but no signs of systemic toxicity.

Genotoxicity studies were conducted with numerous extracts contained in Alyostal Prick and showed no mutagenic or clastogenic potential in *in vitro* assays (using non mammalian and mammalian cells).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride, glycerol, phenol, mannitol, water for injection

Negative control :

Sodium chloride, glycerol, phenol, water for injection

Positive control:

- Codeini phosphas: sodium chloride, glycerol, water for injection
- Histamini dihydrochloridum: sodium chloride, phenol, glycerol, water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years
6 months after first opening

6.4 Special precautions for storage

Store in a refrigerator (2°C – 8°C).
Vial containing positive control with codeine phosphate should be stored below 25°C.

6.5 Nature and contents of container

Carton box (for 6, 20 or 50 vials) which contains type I neutral glass vials with 3 ml solution for skin prick test, each vial stoppered with dropper applicator. Pack size from 1 to 50 vials.

Pack size:

3 ml solution in a 4 ml vial.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

STALLERGENES
6, Rue Alexis de Tocqueville
F-92160 Antony
France

8. MARKETING AUTHORISATION NUMBER(S)

59/241/97-C

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9.4.1997
Renewal of the authorisation: 14.1.2015

10. DATE OF LAST REVISION OF THE TEXT

13. 1. 2026