

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

TRUE Test is used to test for allergic contact dermatitis. Allergic contact dermatitis is a skin reaction caused by exposure to foreign substances resulting in an allergic reaction. These substances might be an ingredient in perfume or aftershave, in an ointment or cream, rubber gloves, industrial chemicals, etc. The substances in TRUE Test are well-known allergens. If a person is allergic to the substance(s) in a particular TRUE Test patch, then the skin under that patch will react to it, becoming red and inflamed. Allergic reactions to more than one patch are possible.

The incidence of allergic contact dermatitis is increasing. It is not understood why certain individuals develop allergic sensitivities. Some people who have a history of seasonal allergies, asthma, atopic dermatitis, eczema, or other skin conditions are more likely to develop contact allergies. In others, repeat exposure of long periods of time to a chemical may result in the development of an allergy. Exposures to new substances, some of allergen nature and part of products used in the daily and occupational environment, have increased. Allergic contact dermatitis can be regarded as wide spread in the population independent of race/ethnic origin.

VI.2.2 Summary of treatment benefits

Allergic contact dermatitis often results in ongoing disease and disability. The condition is not life threatening but can have great influence on the quality of life of the patient. The main treatment option of allergic contact dermatitis is to avoid getting on contact with the specific allergen(s).

If the contact allergy in question can be diagnosed by using TRUE Test, the benefit for the patient is that he/she knows which allergen(s) he/she is allergic to in order to avoid eliciting the respective dermatitis.

VI.2.3 Unknowns relating to treatment benefits

This is not applicable for TRUE Test as it is for diagnostic use.

VI.2.4 Summary of safety concerns

Important identified risks

Safety concern	What is known	Preventability
Flare-up of dermatitis	Patients with a strong positive contact allergy may experience strong patch test reactions and it may lead to transient flare up of previous dermatitis. Uncommon side effect. Non-serious.	Yes, avoid testing during an active phase of dermatitis.
Sensitisation	Sensitization to a substance on the test panel seldom occurs. A test reaction that appear on day 7 or later may be a sign of	No, sensitization is always a risk when performing patch testing.

	contact sensitization. Rare side effect. Non-serious.	
Drug interaction with corticosteroids	Steroids may suppress a positive test reaction.	Yes, avoid use of topical steroids on the test site or oral steroids at least two weeks prior to testing.

Missing information

Safety concern	What is known
Paediatric use	Should not be used. The safety and effectiveness in children have not been established.
Use in pregnancy and while breastfeeding	Should not be used. The safety and effectiveness during pregnancy and while breastfeeding have not been established.

VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post authorisation development plan is applicable.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable as this is the first Risk Management Plan prepared.