

Part VI: Summary of the risk management plan

Summary of risk management plan for Paraben mix allergEAZE 16%, unguento

[methyl-, propyl-, butyl- and ethyl-p-hydroxybenzoate]

This is a summary of the risk management plan (RMP) for Paraben mix allergEAZE 16%, unguento. The RMP details important risks of Paraben mix allergEAZE 16%, unguento, how these risks can be minimised, and how more information will be obtained about Paraben mix allergEAZE 16%, unguento's risks and uncertainties (missing information).

Paraben mix allergEAZE 16%, unguento's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Paraben mix allergEAZE 16%, unguento should be used.

Important new concerns or changes to the current ones will be included in updates of Paraben mix allergEAZE 16%, unguento's RMP.

I. The medicine and what it is used for

Paraben mix allergEAZE 16%, unguento is a medicinal product intended for diagnostic use only. The patch test with Paraben mix allergEAZE 16%, unguento is indicated for the diagnosis of allergic contact dermatitis and photocontact allergy to methyl-, propyl-, butyl-, ethyl-p-hydroxybenzoate in patients with suspected pathology (see SmPC for the full indication). It contains methyl-, propyl-, butyl-, ethyl-p-hydroxybenzoate as the active substances and it is given by cutaneous application by healthcare professionals only.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Paraben mix allergEAZE 16%, unguento, together with measures to minimise such risks and the proposed studies for learning more about Paraben mix allergEAZE 16%, unguento's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Paraben mix allergEAZE 16%, unguento is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Paraben mix allergEAZE 16%, unguento are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Paraben mix allergEAZE 16%, unguento. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	None
Important potential risks	Anaphylactic reaction
Missing information	Use in children and adolescents Pregnancy and lactation

II.B Summary of important risks

Important potential risks

Anaphylactic reaction (severe allergic reaction)	
Evidence for linking the risk to the medicine	Scientific literature
Risk factors and risk groups	Patients with a history of severe allergic reactions
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.8; PIL section 4 <i>Specific clinical measures to address the risk:</i> Recommendation in SmPC section 4.2 and PIL section 3 to only test children in case of strong suspicion of allergic contact dermatitis to methyl-, propyl-, butyl-, ethyl-p-hydroxybenzoate on the basis of a careful medical history. Information about possible symptoms of an anaphylactic shock. Requiring the treating healthcare professional to treat an anaphylactic reaction immediately with rescue medication, and to

	perform therapy according to the results of the consensus conference „acute therapy of anaphylactic reactions“ Legal status: tbd <u>Additional risk minimisation measures:</u> None
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Missing information

Use in children and adolescents	
Evidence for linking the risk to the medicine	There are only few data available on children from clinical trials.
Risk factors and risk groups	Children and adolescents
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.2; PIL section 3 <i>Specific clinical measures to address the risk:</i> Recommendation in SmPC section 4.2.1 and PIL section 3 to only test a limited baseline series in children between 6 and 12 years of age and to only test children under 6 years in case of strong suspicion allergic contact dermatitis to methyl-, propyl-, butyl- and ethyl-p-hydroxybenzoate on the basis of a careful medical history. Legal status: tbd <u>Additional risk minimisation measures:</u> None
Pregnancy and lactation	
Evidence for linking the risk to the medicine	There are only few data available on pregnancy and lactation from clinical trials
Risk factors and risk groups	Unborn and breast-fed children
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC section 4.2; PIL section 2 <i>Specific clinical measures to address the risk:</i> Recommendation in SmPC section 4.6 and PIL section 2 to not carry out during pregnancy or while breastfeeding unless it is considered as absolutely necessary. Legal status: tbd <u>Additional risk minimisation measures:</u> None

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Paraben mix allergEAZE 16%, unguento.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Paraben mix allergEAZE 16%, unguento.