

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento

#### [ p-tert-butylphenol formaldehyde resin (p-t-BPFR)]

This is a summary of the risk management plan (RMP) for Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento. The RMP details important risks of Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento, how these risks can be minimised, and how more information will be obtained about Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento's risks and uncertainties (missing information).

Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento should be used.

Important new concerns or changes to the current ones will be included in updates of Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento's RMP.

#### I. The medicine and what it is used for

Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento is a medicinal product intended for diagnostic use only. The patch test with Resina-p-ter-butilfenolformaldeidica allergEAZE 1% is indicated for the diagnosis of allergic contact dermatitis to p-t-BPFR in patients with suspected pathology (see SmPC for the full indication). It contains p-t-BPFR as the active substance 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 Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento, together with measures to minimise such risks and the proposed studies for learning more about Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, 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 Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, unguento is not yet available, it is listed under 'missing information' below.

## II.A List of important risks and missing information

Important risks of Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, 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 Resina-p-ter-butilfenolformaldeidica allergEAZE 1%, 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 Use during 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 p-t-BPFR on the basis of a careful medical history. SmPC section 4.8 and PIL section 4: Information about possible symptoms of an anaphylactic shock; requirement for 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**

<b>Use in children and adolescents</b>	
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 and PIL section 3 to only test children in case of strong suspicion of allergic contact dermatitis to p-t-BPFR on the basis of a careful medical history.  Legal status: tbd  <u>Additional risk minimisation measures:</u> None
<b>Use during Pregnancy and lactation</b>	
Evidence for linking the risk to the medicine	There are only few data available in pregnant women 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