Part VI: Summary of the risk management plan

Summary of risk management plan for

Antiscabiosum® 10 g/100 g

(Benzylbenzoate)

This is a summary of the risk management plan (RMP) for Antiscabiosum® 10 g/100 g. The RMP details important risks of the product, how these risks can be minimised, and how more information will be obtained about the risks and uncertainties (missing information) of Antiscabiosum® 10 g/100 g.

The summary of product characteristics (SmPC) and the package leaflet (PL) of Antiscabiosum® 10 g/100g gives essential information to healthcare professionals and patients on how the product should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP for Antiscabiosum® 10 g/100 g.

I. The medicine and what it is used for

Antiscabiosum® 10 g/100 g is authorised for the treatment of scabies in children aged 1 to 11 years. It contains benzyl benzoate as the active substance and is applied topically as a white emulsion to the skin. Children aged 1 to 6 years must be treated with Antiscabiosum® 10 g/100 g only, if no additional skin damage is present which may facilitate absorption of benzyl benzoate.

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

Important risks of Antiscabiosum® 10 g/100 g, together with measures to minimise such risks and the proposed studies for learning more about these 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 , including PSUR assessment, if applicable - so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Antiscabiosum® 10 g/100 g 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 Antiscabiosum® 10 g/100 g. 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	None
Missing information	None

II.B Summary of important risks

There are no important risks or missing information.

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 Antiscabiosum® 10 g/100 g.

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

There are no studies required for Antiscabiosum® 10 g/100 g.

Summary of risk management plan for

Antiscabiosum® 25 g/100 g

(Benzylbenzoate)

This is a summary of the risk management plan (RMP) for Antiscabiosum® 25 g/100 g. The RMP details important risks of the product, how these risks can be minimised, and how more information will be obtained about the risks and uncertainties (missing information) of Antiscabiosum® 25 g/100 g.

The summary of product characteristics (SmPC) and the package leaflet (PL) of Antiscabiosum® 25 g/100g gives essential information to healthcare professionals and patients on how the product should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP for Antiscabiosum® 25 g/100 g.

I. The medicine and what it is used for

Antiscabiosum® 25 g/100 g is authorised for the treatment of scabies in adults and adolescents aged 12 years and older. It contains benzyl benzoate as the active substance and is applied topically as a white emulsion to the skin.

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

Important risks of Antiscabiosum® 25 g/100 g, together with measures to minimise such risks and the proposed studies for learning more about these 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, including PSUR assessment, if applicable - so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Antiscabiosum® 25 g/100 g 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 Antiscabiosum® 25 g/100 g for children. 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	None
Missing information	None

II.B Summary of important risks

There are no important risks or missing information.

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 Antiscabiosum® 25 g/100 g.

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

There are no studies required for Antiscabiosum® 25 g/100 g.