

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Infilea 500 mcg/g shampoo (Clobetasol propionate)

This is a summary of the risk management plan (RMP) for *Infilea 500 mcg/g shampoo*. The RMP details important risks of *Infilea 500 mcg/g shampoo*, how these risks can be minimised, and how more information will be obtained about *Infilea 500 mcg/g shampoo*'s risks and uncertainties (missing information).

*Infilea 500 mcg/g shampoo*'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how *Infilea 500 mcg/g shampoo* should be used.

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

*Infilea 500 mcg/g shampoo* is indicated for the topical treatment of moderate scalp psoriasis in adults. It contains clobetasole propionate as the active substance and it is for cutaneous use on the scalp only.

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

Important risks of *Infilea 500 mcg/g shampoo*, together with measures to minimise such risks and the proposed studies for learning more about *Infilea 500 mcg/g shampoo*'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.

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

Important risks of *Infilea 500 mcg/g shampoo* 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 *Infilea 500 mcg/g shampoo*. **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	
<b>Important identified risks</b>	• None
<b>Important potential risks</b>	• None
<b>Missing information</b>	• None

## II.B Summary of important risks

Not applicable.

## II.C Post-authorisation development plan

There are no post-authorisation development plans of the marketing authorisation or specific obligation of *Infilea 500 mcg/g shampoo*.

### 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 *Infilea 500 mcg/g shampoo*.

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

There are no studies required for *Infilea 500 mcg/g shampoo*.