

## Part VI: Summary of the risk management plan

### Summary of risk management plan for Clobetasol propionate 500 micrograms/g shampoo

This is a summary of the risk management plan (RMP) for Clobetasol propionate 500 micrograms/g shampoo. The RMP details important risks of Clobetasol propionate 500 micrograms/g shampoo and how these risks can be minimised.

Clobetasol propionate 500 micrograms/g shampoo summary of product characteristics (SPC) and its package leaflet provide essential information to healthcare professionals and patients on how Clobetasol propionate 500 micrograms/g shampoo should be used.

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

Clobetasol propionate 500 micrograms/g shampoo is indicated for topical treatment of moderate scalp psoriasis in adults. It contains clobetasol propionate as the active substance and it is used by topical route as shampoo.

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

Important risks of Clobetasol propionate 500 micrograms/g shampoo, together with measures to minimise such risks and the proposed studies for further learning on Clobetasol propionate 500 micrograms/g shampoo risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on the correct use, in the package leaflet and SPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of the medicine in a pack is chosen to ensure that the medicine is used correctly (posology, treatment length and method of administration);
- 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.

All together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions, follow-ups, literature cases, signals, are collected continuously and regularly analyzed, including PSUR assessment, so that immediate actions can be taken as necessary. These measures constitute routine pharmacovigilance activities to monitor the risk in order to identify possible changes in the nature, severity or frequency of the events and this, to detect any change to the risk-benefit balance.

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

<b>Summary of safety concerns</b>	
Important identified risks	None
Important potential risks	None
Important missing information	None

## II.B Summary of important risks

The safety information in the proposed product information is aligned to the reference medicinal product.

## II.C Post-authorisation development plan

## II.D Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation for Clobetasol propionate 500 micrograms/g shampoo.

### II.D.1 Other studies in post-authorisation development plan

There are no studies required for Clobetasol propionate 500 micrograms/g shampoo.