Part VI: Summary of the risk management plan

Summary of risk management plan for Calcipotriol + betamethasone dipropionate and calcipotriol containing products

This is a summary of the RMP for Calcipotriol and Calcipotriol + BDP containing products[1]. The RMP details important risks of Calcipotriol and Calcipotriol + BDP containing products, how these risks can be minimised, and how more information will be obtained about risks and uncertainties (missing information).

The summaries of product characteristics (SmPC) and package leaflets (PIL) give essential information to healthcare professionals and patients on how the products should be used.

Important new concerns will be included in updates of the RMP.

I. The medicine and what it is used for

Calcipotriol + BDP and calcipotriol containing products are authorised for topical treatment of psoriasis vulgaris in adults (see SmPC for the full indication). The products contain active substances calcipotriol alone or in combination with BDP.

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

No important risks for Calcipotriol + BDP and calcipotriol containing products have been identified, hence no activities to minimise or further characterise risks are defined.

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;

[1] Enstilar® cutaneous foam also known as Enstilum®; Daivobet® ointment also known as, Dovobet®, Delcibet®, Psorcutan Beta®, Token®, and Taclonex®; Daivobet® gel also known as: Dovobet®, Xamiol®, and Taclonex® (topical suspension); Daivonex® ointment, Daivonex® cream, Daivonex® scalp solution, Daivonex® also known as: Dovonex® and Psorcutan®.

- 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 so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

No important risks and missing information have been identified for Calcipotriol and Calcipotriol + BDP containing products.

Important risks of Calcipotriol and Calcipotriol + BDP containing products 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 the products. 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).

II.B Summary of important risks

Not applicable.

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 obligations for calcipotriol and calcipotriol + BDP containing products.

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

There are no studies required for calcipotriol and calcipotriol + BDP containing products.