Summary of the risk management plan for Calcipotriol/Betamethasone Orifarm

This is a summary of the risk management plan (RMP) for Calciprotriol/Betamethasone Orifarm 50 micrograms/0.5 mg per g gel. The RMP details important risks of Calciprotriol/Betamethasone Orifarm, how these risks can be minimised, and how more information will be obtained about Calciprotriol/Betamethasone Orifarm risks and uncertainties (missing information).

Calciprotriol/Betamethasone Orifarm 50 micrograms/0.5 mg per g gel summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how calcipotriol betamethasone combination should be used.

I. The medicine and what it is used for

Calcipotriol/Betamethasone Orifarm 50 micrograms/0.5 mg per g gel will be used for topical treatment of scalp psoriasis in adults. Topical treatment of mild to moderate "non-scalp" plaque psoriasis vulgaris in adults.

The product contains calcipotriol (as monohydrate) and betamethasone (as dipropionate) as the active substances and it is used topically.

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

Important risks of Calcipotriol/Betamethasone Orifarm, together with measures to minimise such risks and the proposed studies for learning more about Calcipotriol/Betamethasone Orifarm´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 Calcipotriol/Betamethasone Orifarm is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Calciprotriol/Betamethasone Orifarm are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Calciprotriol/Betamethasone Orifarm. 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).

The list of safety concerns published by the CMDh was reviewed (CMDh_330_2015_Rev23_2020_02) and the most recent risks for calcipotriol/betamethasone combination are listed.

Important identified risks	• Skin atrophy • HPA axis suppression • Rebound phenomenon • Secondary infections • Hypercalcaemia
Important potential risks	• Potential enhancement of UV radiation induced skin cancer
Missing information	• Safety and efficacy in children below 18 years • Safety and efficacy in patients with severe renal insufficiency or severe hepatic disorders

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.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 Calcipotriol/Betamethasone Orifarm.

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

There are no studies required for Calcipotriol/Betamethasone Orifarm.