Part VI: Summary of the risk management plan

Summary of risk management plan for Tacrolimus 0.03 % Ointment (tacrolimus)

This is a summary of the risk management plan (RMP) for Tacrolimus 0.03 % Ointment. The RMP details important risks of Tacrolimus 0.03 % Ointment, how these risks can be minimised, and how more information will be obtained about Tacrolimus 0.03 % Ointment's risks and uncertainties (missing information).

Tacrolimus 0.03 % Ointment's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tacrolimus 0.03 % Ointment should be used.

Important new concerns or changes to the current ones will be included in updates of Tacrolimus 0.03 % Ointment's RMP.

II. The medicine and what it is used for

Tacrolimus 0.03 % ointment is indicated in adults, adolescents and children from the age of 2 years.

Flare treatment

Adults and adolescents (16 years of age and above)

Treatment of moderate to severe atopic dermatitis in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids.

Children (2 years of age and above)

Treatment of moderate to severe atopic dermatitis in children who failed to respond adequately to conventional therapies such as topical corticosteroids.

Maintenance treatment

Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).

It contains tacrolimus as the active substance and given by topical route.

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

Important risks of Tacrolimus 0.03 % Ointment, together with measures to minimise such risks and the proposed studies for learning more about Tacrolimus 0.03 % Ointment'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, including PSUR assessment and signal management activity, 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 Tacrolimus 0.03 % Ointment 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 Tacrolimus 0.03 % Ointment. 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);

Important identified risks	• None
Important potential risks	• None

Missing information	• None

II.B Summary of important risks with additional risk minimisation measures

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 Tacrolimus 0.03 % Ointment.

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

There are no studies required for Tacrolimus 0.03 % Ointment.