PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Protopic

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

The Protopic Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Protopic should be used.

This summary of the RMP for Protopic should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Protopic RMP.

I. The medicine and what it is used for

Protopic is authorised for the treatment of moderate to severe AD (see SmPC for the full indication). It contains tacrolimus as the active substance and it is given by topical administration.

Further information about the evaluation of the benefits of Protopic can be found in the Protopic EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000374/human_med_001000.jsp&mid=WC0b01ac058001d124

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

No important risks for Protopic 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;
- 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

No important risks and missing information have been identified for Protopic.

Important risks 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 Protopic.

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).

VI.2.6 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 a specific obligation of Protopic.

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

There are no studies required for Protopic.

Finalised Post authorisation safety studies

Study short name	Purpose of the study	Status
APPLES™ study	Phase 4, prospective, multinational, observational cohort study conducted in	Finalised

	USA, Canada and Europe (DE, IE, UK, PL, AT, FR, NL). The study is investigating long-term safety, primarily risk of developing malignancies.	Final report submission deadline to EMA 30-Sep-2019
JOELLE study	To assess the risk of skin malignancies and lymphoma in children and adults using data from four European health databases (PHARMO Database Network in the Netherlands, the Danish and Swedish national registers, and the Clinical Practice Research Datalink (CPRD)) in the United Kingdom.	Finalised Final report submission deadline to EMA 30-Sep-2019