Part VI: Summary of the risk management plan for Fusidinsyre/betamethasonvalerat “Leo” (fusidic acid and betamethasone valerate)

This is a summary of the risk management plan (RMP) for Fusidinsyre/betamethasonvalerat “Leo” Lipid cream. The RMP details important risks of Fusidinsyre/betamethasonvalerat “Leo”, how these risks can be minimised, and how more information will be obtained about Fusidinsyre/betamethasonvalerat “Leo” risks and uncertainties (missing information).

The summary of product characteristic (SmPC) of Fusidinsyre/betamethasonvalerat “Leo” and its package leaflet give essential information to healthcare professionals and patients on how Fusidinsyre/betamethasonvalerat “Leo” should be used.

Important new concerns or changes to the current ones will be included in updates of the Fusidinsyre/betamethasonvalerat “Leo” RMP.

I. The medicine and what it is used for

Fusidinsyre/betamethasonvalerat “Leo”is authorised for infected atopic dermatitis and dermatitis, especially allergic and toxic eczema infected by microorganisms sensitive to fusidic acid (see SmPC for the full indication). It contains fusidic acid and betamethasone valerate as the active substances and it is applied by topical administration.

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

In this update, all important risks for Fusidinsyre/betamethasonvalerat “Leo” are considered as minimised by the routine measures stated below, therefore no additional 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.

In addition to these measures, information about adverse reactions is collected continuously and is 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 Fusidinsyre/betamethasonvalerat “Leo”.

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 Fusidinsyre/betamethasonvalerat “Leo”.

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 Post-authorisation development plan

II.B.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Fusidinsyre/betamethasonvalerat “Leo”.

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Fusidinsyre/betamethasonvalerat “Leo”.

References

1. Guideline on good pharmacovigilance practices (GVP), Module V – Risk management systems (Rev 2) (2017).