

## **PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN**

### **Summary of risk management plan for Fusidic acid:**

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

Fusidic acid's summary of product characteristics (SmPC) and its package leaflet gives essential information to healthcare professionals and patients on how Fusidic acid should be used.

#### **I. The medicine and what it's used for:**

Fusidic acid is authorised for the topical treatment of infections due to micro-organisms sensitive to this anti-infective, in particular *Staphylococcus aureus*. It contains Fusidic acid as the active substance and it is given by Cutaneous use.

#### **II. Risks associated with the medicine and activities to minimize or further characterize the risks:**

Important risks of Fusidic acid, together with measures to minimize such risks and the proposed studies for learning more about Fusidic acid's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the summary of product characteristics (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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

#### **II.A. List of important risks and missing information**

Important risks of Fusidic acid are risks that need special risk management activities to further investigate or minimize 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 enough proof of a link with the use of Fusidic acid. 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).

**Table 2: Summary of safety concerns**

<b>Important Identified Risks</b>	<ul style="list-style-type: none"><li>• None</li></ul>
<b>Important Potential Risks</b>	<ul style="list-style-type: none"><li>• Hypersensitivity reactions</li></ul>
<b>Missing Information</b>	<ul style="list-style-type: none"><li>• None</li></ul>

**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 required for Fusidic acid.

**II.C.2 Other Studies in Post Authorisation Development Plan**

There are no studies required for Fusidic acid.