Part VI: Summary of the risk management plan

Summary of risk management plan for Etofenamate 70 mg cutaneous patch

This is a summary of the risk management plan (RMP) for *Etofenamate 70 mg cutaneous patch*. The RMP details important risks of *Etofenamate 70 mg cutaneous patch* and how these risks can be minimised.

The summary of product characteristics (SmPC) and package leaflet for the *Etofenamate 70 mg cutaneous patch* give essential information to healthcare professionals and patients on how this product should be used.

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

I. The medicine and what it is used for

Etofenamate 70 mg cutaneous patch is authorised for the treatment of pain and swelling in acute blunt trauma injuries such as ankle sprain. It contains etofenamate as the active substance and is for cutaneous use.

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

Important risks of *Etofenamate 70 mg cutaneous patch*, together with measures to minimise such 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.

II.A List of important risks and missing information

Important risks of *Etofenamate 70 mg cutaneous patch* 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 *Etofenamate 70 mg cutaneous patch*.

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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable.

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 *Etofenamate 70 mg cutaneous patch*.

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

There are no studies required for *Etofenamate 70 mg cutaneous patch*.