

PART VI Summary of the Risk Management Plan

Summary of Risk Management Plan

For

Ibuprofen Nutra Essential

(Ibuprofen)

This is a summary of the risk management plan (RMP) for the abovementioned ibuprofen-containing products.

The RMP details the risks of the abovementioned products, how these risks can be minimized and how more information will be obtained about these products' risks and uncertainties (missing information).

Summary of Product Characteristics (SmPC) for each product and their Package Information Leaflet (PIL) give essential information to healthcare professionals and patients on how these products should be used.

I. The medicine and what it is used for.

Ibuprofen Nutra Essential is used for the short-term symptomatic treatment of mild to moderate pain and for feverish states. This product is recommended for adults and adolescents aged 12 years and over (weight over 40 kg).

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

Main risks of ibuprofen, together with measures to minimise such risks and the proposed studies for learning more about these products' risks, are outlined below.

Measures to minimise the risks identified for these 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.

There are no additional risk minimisation measures in this RMP.

II.A List of important risks and missing information.

Summary of safety concerns	
Important identified risks	-None
Important potential risks	-None
Missing information	-None

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 authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Ibuprofen Nutra Essential.

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

There are no studies required for Ibuprofen Nutra Essential.