

Summary of risk management plan for Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film (Ibuprofen)

This is a summary of the risk management plan (RMP) for Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film. The RMP details important risks of ibuprofen, and how more information will be obtained about Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film risks and uncertainties (missing information).

Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ibuprofen should be used.

Important new concerns or changes to the current ones will be included in updates of Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film RMP.

I. The medicine and what it is used for

Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film is authorised for the symptomatic treatment of mild to moderate pain including migraine headache, primary dysmenorrhoea, and fever. Symptomatic treatment of pain and inflammation in arthritic diseases (e.g. rheumatoid arthritis) degenerative arthritic conditions (e.g. osteoarthritis), and in painful swelling and inflammation after soft tissue injuries (see SmPC for the full indication). It contains ibuprofen as the active substance and it is given by the oral route of administration.

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

Important risks of Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film, together with measures to minimise such risks and the proposed studies for learning more about Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film 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 Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film. 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).

| 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 authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film.

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

There are no studies required for Ibuprofene Laboratori Alter 400 mg and 600 mg compresse rivestite con film.