

Ibumax Lysin 400 mg film-coated tablets

19.11.2020, version: 0.1

PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

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

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

I. The medicine and what it is used for

Ibumax Lysin is authorised for short-term symptomatic treatment of mild to moderate pain, such as headache, menstrual pain, dental pain and/or fever in adults, adolescents and children from 20 kg body weight (aged 6 years and older). It contains ibuprofen as the active substance and it is given by oral route of administration.

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

Important risks of Ibumax Lysin, together with measures to minimise such risks and the proposed studies for learning more about Ibumax Lysin's 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 Ibumax Lysin are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Ibumax Lysin. 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	<ul style="list-style-type: none"> • GI bleeding, ulceration and perforations • Cardiovascular and cerebrovascular events (hypertension, heart failure, arterial thrombotic events) • Hypersensitivity • Hepatic and renal disorders • Use during pregnancy (including risk of premature closure of ductus arteriosus) • Severe skin reactions (Steven Johnson syndrome, epidermal necrolysis) • Interaction with anti-coagulants • Interaction with anti-hypertensives
Important potential risks	<ul style="list-style-type: none"> • Impaired fertility
Missing information	<ul style="list-style-type: none"> • Breast feeding

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 Ibumax Lysin.

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

There are no studies required for Ibumax Lysin.