

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets (Ibuprofen):

This is a summary of the risk management plan (RMP) for Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets. The RMP details important risks of Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets, how these risks can be minimized, and how more information will be obtained about Ibuprofen 200mg, 400mg & 600mg Film-coated Tablet's risks and uncertainties (missing information).

Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Ibuprofen 200mg, 400mg & 600mg Film-coated Tablet's RMP.

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

Ibuprofen 200mg, & 400mg Film-coated Tablets belongs to a class of NSAID, and it is used for the short-term symptomatic treatment of:

- mild to moderate pain
- acute migraine headaches
- fever associated with the common cold.

Ibuprofen 600mg Film-coated Tablets are used for the 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.

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 minimize or further characterize the risks:

Important risks of Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets, together with measures to minimize such risks and the proposed studies for learning more about Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets 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 package leaflet and SmPC addressed to patients and healthcare professionals.
- Important advice on the medicine's packaging;
- The authorized 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 minimization measures.

II.A. List of important risks and missing information

Important risks of Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets are risks that need special risk

management activities to further investigate or minimize 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 Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets. 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">• None
Important Potential Risks	<ul style="list-style-type: none">• None
Missing Information	<ul style="list-style-type: none">• 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 Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets.

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

There are no studies required for Ibuprofen 200mg, 400mg & 600mg Film-coated Tablets.