

Part VI: Summary of the risk management plan

Summary of risk management plan for Ibudol 200 mg coated tablets and Ibudol 400 mg film coated tablets (ibuprofen)

This is a summary of the risk management plan (RMP) for Ibuprofen 200 mg tablets and 400 mg film coated tablets. The RMP details important risks of Ibudol 200 mg coated tablets and Ibudol 400 mg film coated tablets, how these risks can be minimised, and how more information will be obtained about Ibuprofen's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

The proposed indications for Ibudol 200 mg coated tablets and Ibudol 400 mg film coated tablets are: treatment of pain of different origin and nature (headache, toothache, neuralgia, osteo-articular and muscular pain, menstrual pain) and adjuvant in the treatment symptomatic of febrile and flu (see SmPC for the full indication). 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 Ibuprofen, together with measures to minimise such risks and the proposed studies for learning more about Ibuprofen'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.

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 Ibuprofen 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 Ibuprofen. 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"> • Hypersensitivity/allergic reactions • Use during third trimester of pregnancy (premature ductus arteriosus closure) • Gastrointestinal bleeding, ulceration and perforation • Cardiovascular events/disorders • Cerebrovascular accident • Hypersensitivity to other NSAIDs or low doses acetylsalicylic acid (increased bleeding and/or ulceration following concomitant administration) • Haematological effects/disorders • Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, exfoliative dermatitis • Renal toxicity • Hepatic impairment • Bronchospasm in patients with asthma or allergic disease • Aseptic meningitis (in patients with SLE and mixed connective tissue disease)
Important potential risks	<ul style="list-style-type: none"> • Impaired female fertility • Influence of the NSAIDs on the deterioration of the course of infections • Use during early pregnancy (foetal cardiac malformation, gastroschisis and miscarriage) • Misuse (e.g. use in children less than 12

List of important risks and missing information	
	years of age)
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

Not applicable.