## Part VI: Summary of the risk management plan

# Summary of risk management plan for Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablets (Ibuprofen)

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

Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablet's RMP.

### I. The medicine and what it is used for

Ibuprofen Accord authorised for following indication:

Ibuprofen Accord 200 mg and 400 mg film coated tablets:

In adults and children: Short term treatment of fever and pain of mild to moderate intensity, including dysmenorrhea [200 mg film coated tablets for over 6 years (>20 kg), 400 mg film coated tablets for over 12 years (>40 kg)].

Long term symptomatic treatment of pain and inflammation in chronic inflammatory rheumatic diseases

Ibuprofen Accord 600 mg film coated tablets:

Symptomatic treatment of pain and inflammation in rheumatoid arthritis (including systemic Juvenile Idiopathic Arthritis [sJIA]), osteoarthritis, seronegative arthropathies and in painful swelling and inflammation after soft tissue injuries.

It contains ibuprofen as the active substance and it is for oral use only.

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

Important risks of Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablets' 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 including PSUR assessment, 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 Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablets 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 Accord 200 mg, 400 mg and 600 mg 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).

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|---|---|
| Important Identified Risk | • None |
| Important Potential Risk | • 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 authorization or specific obligation of Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablets.

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

There are no studies required for Ibuprofen Accord 200 mg, 400 mg and 600 mg film-coated tablets as post-authorisation development plan.