Summary of risk management plan for Ibuprofen B. Braun 4 mg/ml (200 mg) solution for infusion, Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion (ibuprofen)

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This is a summary of the risk management plan (RMP) for Ibuprofen B. Braun 4 mg/ml (200 mg) solution for infusion, Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion. The RMP details important risks of the products, and how more information will be obtained about the products' risks and uncertainties (missing information).

Ibuprofen B. Braun 4 mg/ml (200 mg) solution for infusion, Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how the products should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP.

I. The medicine and what it is used for

Ibuprofen B. Braun 4 mg/ml (200 mg) solution for infusion is authorised in children (≥ 5 kg bodyweight) and adolescents for the short-term symptomatic treatment of acute moderate pain and for the short-term symptomatic treatment of fever, when administration by intravenous route is clinically justified, when other routes of administration are not possible (see SmPC for the full indication).

Ibuprofen B. Braun 400 mg solution for infusion is authorised in adults for the short-term symptomatic treatment of acute moderate pain and for the treatment of fever, when administration by intravenous route is clinically justified and/or when other routes of administration are not possible (see SmPC for the full indication).

Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion is authorised in adults for the short-term symptomatic treatment of acute moderate pain, when administration by intravenous route is clinically justified and/or when other routes of administration are not possible (see SmPC for the full indication).

The products contain ibuprofen as the active substance and they are given by intravenous infusion.

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

Important risks of Ibuprofen B. Braun 4 mg/ml (200 mg) solution for infusion, Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about the products' 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 of Ibuprofen B. Braun 4 mg/ml (200 mg) solution for infusion, Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion 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 the medicinal product. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable, as there are no important risks for Ibuprofen B. Braun 4 mg/ml (200 mg) solution for infusion, Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion.

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 B. Braun 4 mg/ml (200 mg) solution for infusion, Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion.

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

There are no studies required for Ibuprofen B. Braun 4 mg/ml (200 mg) solution for infusion, Ibuprofen B. Braun 400 mg solution for infusion and Ibuprofen B. Braun 600 mg solution for infusion.