PART VI: Summary of the risk management plan

Summary of risk management plan for Paracetamol 10 mg/ml & Ibuprofen (as sodium dihydrate) 3 mg/ml solution for infusion

This is a summary of the risk management plan (RMP) for paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion. The RMP details important risks of paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion, how these risks can be minimised, and how more information will be obtained about the risks and uncertainties (missing information) of paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion.

The summary of product characteristics (SmPC) and package leaflet of paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion give essential information to healthcare professionals and patients on how paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion should be used.

Important new concerns or changes to the current ones will be included in updates of the RMP for paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion.

I. The medicine and what it is used for

Paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion is authorised in adults for the short-term symptomatic treatment of acute moderate pain, where an intravenous route of administration is considered clinically necessary and/or when other routes of administration are not possible. It contains paracetamol and ibuprofen as the active substances and it is given by intravenous infusion administration.

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

Important risks of paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion, together with measures to minimise such risks and the proposed studies for learning more about the risks of paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion, 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.

If important information that may affect the safe use of paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion is not yet available, it is listed under 'missing information' below.

II.A List of important risks and information

Important risks of paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml 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 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 paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion. 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).

There are no important risks or missing information associated with this medicinal product.

II.B Summary of important risks

There are no important risks or missing information associated with this 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 paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion.

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

There are no studies required for paracetamol 10 mg/ml and ibuprofen (as sodium dihydrate) 3 mg/ml in 100 ml solution for infusion.