Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for Ibuprofen/Paracetamol INN-FARM 200 mg/500 mg film-coated tablets.

The RMP details important risks of for Ibuprofen/Paracetamol INN-FARM 200 mg/500 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained regarding unknown risks and uncertainties (missing information) for the Ibuprofen/Paracetamol INN-FARM 200 mg/500 mg film-coated tablets.

Product information of the medicinal product containing ibuprofen/paracetamol 200 mg/500 mg, the Summary of product characteristics (SmPC) and the package leaflet provide an essential information to healthcare professionals and patients regarding the appropriate use of Ibuprofen/Paracetamol INN-FARM 200 mg/500 mg film-coated tablets.

I. The medicine and what it is used for

Ibuprofen/Paracetamol INN-FARM 200 mg/500 mg film-coated tablets is intended for short-term treatment of pain and/or fever. Ibuprofen and paracetamol are the paramount treatment of mild to moderate pain and fever and are therefore an optimal choice for a fixed dose combination of two analgesics/antipyretics.

It represents a fixed combination medicinal product with no new active substance-ibuprofen/paracetamol (200 mg/500 mg), and it is intended to be administered orally.
The lowest effective dose should be used for the shortest time duration necessary to control symptoms.

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

Important risks of Ibuprofen/Paracetamol INN-FARM 200 mg/500 mg film-coated tablets, together with measures to minimise such risks, are outlined below.
Measures to minimise the risks identified for medicinal products are:

- 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.

II.A List of important risks and missing information

No significant risks and missing information have been identified for this medicine.

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 imposed as a condition of the marketing authorisation or specific obligations of Ibuprofen/Paracetamol INN-FARM 200 mg/500 mg film-coated tablets.

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

There are no studies required for Ibuprofen/Paracetamol INN-FARM 200 mg/500 mg film-coated tablets.