

## **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.