PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for ibuprofen film coated tablets:

It belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) which work by inhibition of prostaglandin synthesis. Ibuprofen reduces inflammatory pain, swellings and fever

This is a summary of the risk management plan (RMP) for Ibuprofen 200mg, 400mg,600mg and 800 mg film-coated tablets. The RMP details important risks of Ibuprofen, how these risks can be minimized and how more information will be obtained about Ibuprofen's risks and uncertainties (missing information). Ibuprofen's summary of product characteristics (SmPC)[1] and its package leaflet[2] give essential

information to healthcare professionals and patients on how ibuprofen should be used.

I. The medicine and what it's used for:

Ibuprofen film coated tablets 200mg, 400mg, 600mg & 800mg contains the propionic acid derivative p-isobutyl-hydrothropic acid and it is given by orally.
Ibuprofen belongs to a group of medicines called NSAIDs and contains ibuprofen. Ibuprofen reduces pain, fever and has an anti-inflammatory effect.
Ibuprofen 200 mg & 400 mg is used for the short-term symptomatic treatment of:
- mild to moderate pain such as headache, migraine pain, period pain, dental pain.
- fever.
Ibuprofen 600 mg & 600 mg: In adults it is used for the symptomatic treatment of pain and inflammation in arthritic diseases (e.g. rheumatoid arthritis), degenerative arthritic conditions (e.g. osteoarthritis), and in painful swelling and inflammation after soft tissue injuries.

It is given by the oral route.

II. Risks associated with the medicine and activities to minimize or further characterize the risks:

Important risks of ibuprofen, together with measures to minimize such risks and the proposed studies for learning more about ibuprofen's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the summary of product characteristics (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 minimize its risks.

Together, these measures constitute routine risk minimization measures.

II.A. List of important risks and missing information

Important risks of ibuprofen are risks that need special risk management activities to further investigate or minimize 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 enough proof of a link with the use of ibuprofen. 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).

Table 2: Summary of safety concerns

Important Identified Risks
None
Important Potential Risks
None
Missing Information
None

II.B. Summary of important risks

No additional pharmacovigilance activities or risk minimisation measures are required for this product as there are no safety concerns.

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.

II.C.2 Other Studies in Post Authorisation Development Plan

There are no studies required for ibuprofen.