PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for

Algofrencaps 400 mg, zachte capsules

This is a summary of the risk management plan (RMP) for **Algofrencaps 400 mg, zachte capsules**. The RMP details important risks of **Algofrencaps 400 mg, zachte capsules**, how these risks can be minimised and how more information will be obtained about **Algofrencaps 400 mg, zachte capsules** ' risks and uncertainties (missing information).

Algofrencaps 400 mg, zachte capsules's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how **Algofrencaps 400 mg, zachte capsules** should be used.

Important new concerns or changes to the current ones will be included in updates of **Ibuprofen Algofrencaps 400 mg, zachte capsules**' RMP.

I. The medicine and what it is used for

Algofrencaps 400 mg, zachte capsules is indicated for use in adults, children and adolescents with a body weight of 40 kg or more (12 years of age and above) for the short-term symptomatic treatment of mild to moderate pain such as headache, menstrual pain, dental pain, fever and pain associated with the common cold.

It contains ibuprofen as the active substance and it is given by oral route.

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

Important risks of **Algofrencaps 400 mg, zachte capsules**, together with measures to minimise such risks and the proposed studies for learning more about **Algofrencaps 400 mg, zachte capsules** 's 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 - 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 **Algofrencaps 400 mg, zachte capsules** 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 **Algofrencaps 400 mg, zachte capsules**. 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 SVIII.1: Summary of safety concerns

Important Identified Risks	• None
Identified potential risks	• None
Missing information	• None

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 which are conditions of the marketing authorisation or specific obligation of **Algofrencaps 400 mg, zachte capsules**.

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

There are no studies required for **Algofrencaps 400 mg, zachte capsules**.