Part VI: Summary of the risk management plan for Triplo, acetylsalicylic acid/caffeine

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

Triplo's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Triplo should be used.

I. The medicine and what it is used for

Triplo is authorised for mild pain and migraine (see SmPC for the full indication). It contains acetylsalicylic acid and caffeine as the active substances and it is given orally as tablets.

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

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

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the Danish Medicines Agency.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of Triplo 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 Triplo. 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);

Summary of safety concerns	
Important identified risks	• Gastrointestinal Haemorrhage • Haemorrhage • Hypersensitivity reactions • Gastric or Duodenal Ulcer • Severe Cutaneous Adverse Reactions • Deterioration of Renal Function • Medication overuse headache • Drug-drug interactions • Deterioration of hepatic function • Long term use in the elderly
Important potential risks	• Reye's Syndrome • Overdose
Missing information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the product information of Treo in Denmark.

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 Triplo.

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

There are no studies required for Triplo.