PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN
Summary of risk management plan for acetylsalicylic acid 75 mg film-coated tablets (acetylsalicylic acid)

This is a summary of the risk management plan (RMP) for Acetylsalicylic acid 75 mg film-coated tablets (hereafter referred as Acetylsalicylic acid film-coated tablets). The RMP details important risks of Acetylsalicylic acid film-coated tablets, how these risks can be minimised, and how more information will be obtained about Acetylsalicylic acid film-coated tablets' risks and uncertainties (missing information).

Acetylsalicylic acid film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Acetylsalicylic acid film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Acetylsalicylic acid film-coated tablet's RMP.

I. The medicine and what it is used for
Acetylsalicylic acid 75 mg film-coated tablets is used for:
- Secondary prevention of myocardial infarction.
- Prevention of cardiovascular morbidity in patients suffering from stable angina pectoris.
- History of unstable angina pectoris, except during the acute phase.
- Prevention of graft occlusion after Coronary Artery Bypass Grafting (CABG).
- Coronary angioplasty, except during the acute phase.
- Secondary prevention of transient ischaemic attacks (TIA) and ischaemic cerebrovascular accidents (CVA), provided intracerebral haemorrhages have been ruled out.
- Acute Myocardial infarction

It contains acetylsalicylic acid 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 when taking Acetylsalicylic acid film-coated tablets, together with measures to minimise such 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 Acetylsalicylic acid film-coated tablets 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 Acetylsalicylic acid film-coated tablets. 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).

List of important risks and missing information	
Important identified risks	• None
Important 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 Acetylsalicylic acid film-coated tablets.

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

There are no studies required for Acetylsalicylic acid film-coated tablets.