Summary of risk management plan for *Acetylsalicylic acid tablets* (acetylsalicylic acid)

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

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

Important new concerns or changes to the current ones will be included in updates of *Acetylsalicylic acid tablets*' RMP.

I. The medicine and what it is used for

Acetylsalicylic acid tablets are authorised for

- Acute myocardial infarction.
- 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.

It contains acetylsalicylic acid as the active substance and it is given orally. *Acetylsalicylic acid tablets* are available in strengths of 75 mg and 160 mg tablets.

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

Important risks of *Acetylsalicylic acid tablets*, together with measures to minimise such risks and the proposed studies for learning more about *Acetylsalicylic acid tablets*' 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 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 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

Not applicable. No risks relevant for this risk minimisation plan are proposed for *Acetylsalicylic acid tablets.*

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 tablets*.

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

There are no studies required for *Acetylsalicylic acid tablets*.