Part VI: Summary of the risk management plan for acetylsalicylic acid, 75 mg, and 100 mg, gastro-resistant table

This is a summary of the RMP for acetylsalicylic acid, 75 mg, and 100 mg, gastro-resistant tablets. The RMP details important risks of acetylsalicylic acid, gastro-resistant tablets, how these risks can be minimized, and how more information will be obtained about acetylsalicylic acid, gastroresistant tablet's risks and uncertainties (missing information).

Acetylsalicylic acid, gastro-resistant tablets summaries of product characteristics and its package leaflets give essential information to healthcare professionals and patients on how acetylsalicylic acid, gastro-resistant tablets should be used.

Important new concerns or changes to the current ones will be included in updates of acetylsalicylic acid, gastro-resistant tablet's RMP.

I. The medicine and what it is used for

Acetylsalicylic acid, gastro-resistant tablets are authorized for:
Acetylsalicylic acid is restricted to secondary prevention with chronic treatment in adults and adolescents (aged 16 years and older):

- 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 ischemic attacks (TIA) and ischemic cerebrovascular accidents (CVA) provided intracerebral hemorrhages have been ruled out.

Acetylsalicylic acid is not recommended in emergency situations.
It contains acetylsalicylic acid as the active substance and is given orally as gastro resistant tablets (75 mg and 100 mg).

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

Important risks acetylsalicylic acid, gastro-resistant tablets, together with measures to minimize such risks and the proposed studies for learning more about acetylsalicylic acid, gastro-resistant tablet'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 prescribing information and SmPC addressed to patients and healthcare professionals.
- Important advice on the medicine's packaging.
- The authorized 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed 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, gastro-resistant tablets are risks that need special risk management activities to further investigate or minimize 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, gastroresistant 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).

Table 3 – Part VI: 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.

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of acetylsalicylic acid, gastro-resistant tablets.

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

There are no studies required for acetylsalicylic acid, gastro-resistant tablets.