Summary of risk management plan for Acetylsalicylic Acid Bluefish (acetylsalicylic acid)

This is a summary of the risk management plan (RMP) for Acetylsalicylic acid Bluefish. The RMP details important risks of Acetylsalicylic acid Bluefish, which can be minimized through routine risk minimization measures, and more information will be obtained about Acetylsalicylic acid Bluefish's risks and uncertainties (missing information) through routine pharmacovigilance activities.

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Acetylsalicylic acid Bluefish is authorised for Acute myocardial infarction. Prophylaxis of cardiovascular complications after acute myocardial infarction and for unstable coronary syndromes (unstable angina pectoris, completed non-Q-wave myocardial infarction) and stable angina pectoris.

Secondary prophylaxis against recurrence of cerebrovascular disease such as TIA (transient ischaemic attacks) and RIND (reversible ischaemic neurological defect). It contains acetylsalicylic acid as the active substance, and it is given by orally in tablet form and available in 75mg and 160 mg strength.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Acetylsalicylic Acid Bluefish, together with measures to minimise such risks and the proposed studies for learning more about Acetylsalicylic Acid Bluefish'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.

II.A List of important risks and missing information

Important risks of Acetylsalicylic Acid Bluefish 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 Bluefish. 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 Trombyl, Pfizer AB.

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 Bluefish.

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

There are no studies required for Acetylsalicylic Acid Bluefish.