Part VI: Summary of the risk management plan

This Summary of the risk management plan is applicable to Ticagrelor Devatis 60 mg and 90 film-coated tablets.

Summary of risk management plan for Ticagrelor Devatis 60 mg and 90 film-coated tablets (Ticagrelor)

This is a summary of the risk management plan (RMP) for Ticagrelor Devatis 60 mg and 90 film-coated tablets. The RMP details important risks of Ticagrelor Devatis 60 mg and 90 film-coated tablets, how these risks can be minimised, and how more information will be obtained about Ticagrelor Devatis 60 mg and 90 film-coated tablet's risks and uncertainties (missing information).

Ticagrelor Devatis 60 mg and 90 film-coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ticagrelor Devatis 60 mg and 90 film-coated tablets should be used.

I. The medicine and what it is used for

Ticagrelor Devatis 60 mg and 90 film-coated tablets, co-administered with acetylsalicylic acid (ASA),is authorised for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (ACS) or a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event (see SmPC for the full indication). It contains ticagrelor as the active substance and it is given orally.

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

Important risks of Ticagrelor Devatis 60 mg and 90 film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Ticagrelor Devatis 60 mg and 90 film-coated tablets and 90 mg orodispersible tablet'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.

If important information that may affect the safe use of Ticagrelor Devatis 60 mg and 90 film-coated tablets is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Ticagrelor Devatis 60 mg and 90 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 Ticagrelor Devatis 60 mg and 90 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	Increased risk of bleeding
Important potential risks	None
Missing information	Long-term use in patients with prior ischaemic stroke

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 Ticagrelor Devatis 60 mg and 90 film-coated tablets.

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

There are no studies required for Ticagrelor Devatis 60 mg and 90 film-coated tablets.