## PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

### Summary of risk management plan for Prasugrel 5 mg and 10 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Prasugrel 5 mg/ 10 mg film-coated tablets. The RMP details important risks of Prasugrel 5 mg/ 10 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Prasugrel 5 mg/ 10 mg film-coated tablets' risks and uncertainties (missing information).
Prasugrel 5 mg/ 10 mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Prasugrel 5 mg/ 10 mg film-coated tablets should be used.

### I. The medicine and what it is used for

Prasugrel 5 mg/ 10 mg film-coated tablets are indicated for:
Prasugrel, co-administered with acetylsalicylic acid (ASA), is authorised for the prevention of atherothrombotic events in patients with acute coronary syndrome (i.e., unstable angina, non-ST segment elevation myocardial infarction [UA/NSTEMI] or ST segment elevation myocardial infarction [STEMI]) undergoing primary or delayed percutaneous coronary intervention. It contains prasugrel as the active substance and it is given by film-coated tablets available in 5 mg and 10 mg strength.

### II.A List of important risks and missing information

Important risks of Prasugrel 5 mg/ 10 mg 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 Prasugrel 5 mg/ 10 mg 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** | • Colorectal Cancer |
| **Missing Information** | • None |

## II.B Summary of important risks

| **Important potential risks: Colorectal Cancer** | |
|---|---|
| Risk minimisation measures | Specific follow-up form for colorectal cancer |

## 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 for Prasugrel 5 mg and 10 mg film-coated tablets.

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

There are no studies required for Prasugrel 5 mg and 10 mg film-coated tablets.