Part VI: Summary of the risk management plan

Summary of risk management plan for Prafsia 5mg, 10mg film-coated tablets (prasugrel)

This is a summary of the risk management plan (RMP) for Prafsia 5mg, 10mg film-coated tablets. The RMP details important risks of Prafsia 5mg, 10mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Prafsia's 5mg, 10mg film-coated tablets risks and uncertainties (missing information).

Prafsia's 5mg, 10mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Prafsia 5mg, 10mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Prafsia 5mg, 10mg film-coated tablets' RMP.

I. The medicine and what it is used for

Prafsia co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult 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 (PCI).

It contains prasugrel 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 Prafsia 5mg, 10mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Prafsia's 5mg, 10mg film-coated 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 the case of Prafsia 5mg, 10mg film-coated tablets, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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.

If important information that may affect the safe use of Prafsia 5mg, 10mg 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 Prafsia 5mg, 10mg 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 Prafsia 5mg, 10mg filmcoated 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	• Bleeding - Intracranial haemorrhage - Gastrointestinal haemorrhage - Intraocular haemorrhage - Epistaxis - PCI-related haemorrhage - CABG-related haemorrhage - Associated with prasugrel use prior to coronary angiography in NSTEMI patients - Other procedure-related haemorrhage including angioedema • Hypersensitivity including angioedema • Thrombocytopenia • Thrombotic thrombocytopenic purpura
Important potential risks	• Potential off-label use in patients with prior TIA/stroke • Drug-induced hepatic injury • Colorectal cancer
Missing information	• Concomitant use with fibrinolytics, other thienopyridines, warfarin, and chronic use of NSAIDs (non-ASA) • Paediatric population • Pregnant/lactating women • Subjects without clinical manifestation of ACS • Subjects with severely compromised cardiac status (cardiogenic shock, class IV CHF, refractory ventricular arrhythmia) • Subjects with severe hepatic impairment

II.B Summary of important risks

Important identified risk: Bleeding *(intracranial haemorrhage, gastrointestinal haemorrhage, intraocular haemorrhage, epistaxis, PCI-related haemorrhage, CABG-related haemorrhage, Associated with prasugrel use prior to coronary angiography in NSTEMI patients, Other procedure-related haemorrhage including angioedema)*	
Risk minimisation measures	*Routine risk minimisation measures:* SmPC sections 4.2, 4.3, 4.4 and 4.8 PIL sections 2 and 4 Pack size Aluminium foil blisters in cartons of 28, 30, 56 and 98 tablets.

	Not all pack sizes may be marketed. *Additional risk minimisation measures:* HCP Educational Material

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 Prafsia 5mg, 10 mg film-coated tablets.

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

There are no studies required for Prafsia 5mg, 10 mg film-coated tablets.