Part VI: Summary of risk management plan

Summary of risk management plan for Clopidogrel 75mg Film coated tablets

This is a summary of the risk management plan (RMP) for Clopidogrel 75 mg Film coated tablets. The RMP details important risks of Clopidogrel 75 mg Film coated tablets, how these risks can be minimised, and how more information will be obtained about Clopidogrel 75 mg Film coated tablets risks and uncertainties (missing information).

Clopidogrel 75 mg Film coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Clopidogrel 75 mg Film coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Clopidogrel 75 mg Film coated tablet's RMP.

I. The medicine and what it is used for

Secondary prevention of atherothrombotic events
Clopidogrel 75 mg Film coated tablet is indicated for:
• Adult patients suffering from myocardial infarction (from a few days until less than 35 days), ischemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease.
• Adult patients suffering from acute coronary syndrome:
- Non-ST segment elevation acute coronary syndrome (unstable angina or non-Q-wave myocardial infarction), including patients undergoing a stent placement following percutaneous coronary intervention, in combination with acetylsalicylic acid (ASA).
- ST segment elevation acute myocardial infarction, in combination with ASA in medically treated patients eligible for thrombolytic therapy.

In patients with moderate to high-risk Transient Ischaemic Attack (TIA) or minor Ischaemic Stroke (mIS)
Clopidogrel in combination with ASA is indicated in:
- Adult patients with moderate to high-risk TIA (ABCD21 score ≥4) or minor IS (NIHSS2 ≤3) within 24 hours of either the TIA or mIS event.

Prevention of atherothrombotic and thromboembolic events in atrial fibrillation
In adult patients with atrial fibrillation who have at least one risk factor for vascular events, are not suitable for treatment with Vitamin K antagonists (VKA) and who have a low bleeding risk, clopidogrel is indicated in combination with ASA for the prevention of atherothrombotic and thromboembolic events, including stroke.

It contains Clopidogrel as the active substance and it is given by oral route of administration.

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

Important risks of Clopidogrel 75 mg Film coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Clopidogrel 75 mg Film coated 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.

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.

II.A List of important risks and missing information

Important risks of Clopidogrel 75 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 administered. 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 Clopidogrel 75 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	• Major bleeding (including ICH[a])
Important potential risks	• None
Missing information	• None

[a] ICH (= Intracranial Haemorrhage) is applicable especially in the Transient Ischemic Attack (TIA) / Minor Ischaemic Stroke (mIS) indication of Dual Antiplatelet Therapy (DAPT) for the first 21 days after TIA/mIS events, this indication cumulating multiple risks of bleeding particularly in patients ≥75 years of age.

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 Clopidogrel 75 mg Film coated tablets.

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

There are no studies required for Clopidogrel 75 mg Film coated tablets.