Part VI: Summary of the risk management plan

Summary of risk management plan for Clopidogrel Amarox.

This is a summary of the risk management plan (RMP) for Clopidogrel Amarox. The RMP details important risks of Clopidogrel Amarox, risk minimisation measures needed to minimise these risks and routine pharmacovigilance activities needed to obtain more information about Clopidogrel Amarox risks and uncertainties (missing information).

Clopidogrel Amarox Summary of product characteristics gives essential information to healthcare professionals and patients on how Clopidogrel Amarox should be used.

Important new concerns or changes to the current ones will be included in updates of Clopidogrel Amarox's RMP.

I. The medicine and what it is used for

Clopidogrel Amarox is indicated for secondary prevention of atherothrombotic events in recent MI, recent IS or established PAD and moderate to high-risk TIA or minor IS, and in ACS. It is also indicated for the prevention of atherothrombotic and thromboembolic events in atrial fibrillation (see SmPC for the full indication).

It contains Clopidogrel Amarox (as Clopidogrel hydrogen sulphate) as the active substance and it is given by orally.

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

Important risks of Clopidogrel Amarox, together with measures to minimise such risks and learning more about Clopidogrel Amarox 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 leaflets and SmPCs 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 Clopidogrel Amarox 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 Amarox.

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.

List of important risks and missing information	
Important identified risks	Major bleeding (including ICH*)
Important potential risk	None
Missing information	None

* ICH is applicable especially in TIA/MS indication of DAPT for the first 21 days after TIA/MS events, this indication cumulating multiple risks of bleeding particularly in patients ≥75 years of age.
DAPT: Dual Antiplatelet Therapy; ICH: Intracranial Hemorrhage; MS: Multiple Sclerosis; TIA: Transient Ischemic Attack

II.B Summary of important risks

The safety information in the proposed Summary of product characteristics, Labelling and Package information leaflet is aligned to the reference medicinal product.

II.C Post-authorisation development plan

No post authorisation study is planned for this product.

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or which are a specific obligation of Clopidogrel Amarox.

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

There are no studies required for Clopidogrel Amarox.