Part VI: Summary of the risk management plan

Plan for Amlodipine Oral Suspension

This is a summary of the risk management plan (RMP) for Amlodipine oral suspension. The RMP details important risks of Amlodipine oral suspension, how these risks can be minimised, and how more information will be obtained about Amlodipine's risks and uncertainties (missing information).

Amlodipine's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Amlodipine should be used.

I. The medicine and what it is used for

Amlodipine Oral Suspension is to be authorized for the treatment of hypertension, chronic stable angina pectoris and vasospastic (Prinzmetal's) angina. The active substance is amlodipine besilate and the medicinal product is administered by oral administration.

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

Important risks of Amlodipine, together with measures to minimise such 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, including PSUR assessment - 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 Amlodipine is not yet available, it is listed under 'missing information' below.

II.A Summary of safety concerns and missing information

Important risks of Amlodipine 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 Amlodipine. 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);

Summary of safety concerns	
Important identified risks	Pulmonary oedema Use in patients with impaired hepatic function Risk of cardiovascular events Drug interaction with CYP3A4 inhibitors
Important potential risks	Use in elderly patients Effect on male infertility Medication failure (underdosing from failure to shake the bottle well before use)
Missing information	Use in pregnancy and lactation Use in paediatric patients under 6 years old Use in hypertensive crisis

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

Not applicable.

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

Not applicable.