Part VI: Summary of the risk management plan

Summary of risk management plan for Amlodipin Medical Valley (Amlodipine besilate)

This is a summary of the risk management plan (RMP) for Amlodipin Medical Valley. The RMP details important risks of Amlodipin Medical Valley and how more information will be obtained about Amlodipin Medical Valley's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Amlodipin Medical Valley's RMP.

I. The medicine and what it is used for

Amlodipin Medical Valley is authorised for hypertension, chronic stable angina pectoris and vasospastic (Prinzmetal's) angina (see SmPC for the full indication). It contains Amlodipine besilate as the active substance and it is given by tablet.

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

Important risks of Amlodipin Medical Valley, together with measures to minimise such risks and the proposed studies for learning more about Amlodipin Medical Valley'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*.

If important information that may affect the safe use of Amlodipin Medical Valley is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Amlodipin Medical Valley 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 Amlodipin Medical Valley. 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 fertility
Missing information	• Use in pregnancy and lactation • Use in paediatric patients under 6 years of age • 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

Not applicable.

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

Not applicable.

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

There are no studies required for Amlodipin Medical Valley.