Part VI: Summary of the risk management plan

Summary of risk management plan for Cardene IV, 1 mg/ml oplossing voor infusie (nicardipine hydrochloride)

This is a summary of the risk management plan (RMP) for Cardene IV, 1 mg/ml oplossing voor infusie. The RMP details important risks of Cardene IV, 1 mg/ml oplossing voor infusie, how these risks can be minimised, and how more information will be obtained about Cardene IV, 1 mg/ml oplossing voor infusie's risks and uncertainties (missing information).

Cardene IV, 1 mg/ml oplossing voor infusie's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Cardene IV, 1 mg/ml oplossing voor infusie should be used.

Important new concerns or changes to the current ones will be included in updates of Cardene IV, 1 mg/ml oplossing voor infusie's RMP.

I. The medicine and what it is used for

Cardene IV, 1 mg/ml oplossing voor infusie is authorised for the treatment of acute life-threatening hypertension, particularly in the event of:

- Malignant arterial hypertension/Hypertensive encephalopathy
- Aortic dissection, when short acting beta-blocker therapy is not suitable, or in combination with a beta-blocker when beta-blockade alone is not effective
- Severe pre-eclampsia, when other intravenous antihypertensive agents are not recommended or are contra-indicated.

Nicardipine is also indicated for the treatment of post-operative hypertension (see SmPC for the full indication). It contains nicardipine hydrochloride as the active substance and it is given by continuous intravenous infusion.

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

Important risks of Cardene IV, 1 mg/ml oplossing voor infusie, together with measures to minimise such risks and the proposed studies for learning more about Cardene IV, 1 mg/ml oplossing voor infusie'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, including PSUR assessment, 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 Cardene IV, 1 mg/ml oplossing voor infusie 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 Cardene IV, 1 mg/ml oplossing voor infusie. 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 paediatric use of the medicine);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable.

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 Cardene IV, 1 mg/ml oplossing voor infusie.

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

There are no studies required for Cardene IV, 1 mg/ml oplossing voor infusie.