Part VI: Summary of the risk management plan

Summary of risk management plan for nicardipine (nicardipine hydrochloride)

This is a summary of the risk management plan (RMP) for Nicardipine Aguettant 1mg/ml solution for infusion. The RMP details if any important risks of Nicardipine Aguettant 1mg/ml solution for infusion, and how more information will be obtained about Nicardipine Aguettant 1mg/ml solution for 's risks and uncertainties (missing information).

Nicardipine Aguettant 1mg/ml solution for infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Nicardipine Aguettant 1mg/ml solution for infusion should be used.

I. The medicine and what it is used for

Nicardipine Aguettant 1mg/ml solution for infusion 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; or 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 only.

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

Important risks of Nicardipine Aguettant 1mg/ml solution for infusion, together with measures to minimise such risks are outlined below if any.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the 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.

If important information that may affect the safe use of Nicardipine Aguettant 1mg/ml solution for infusion is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Nicardipine Aguettant 1mg/ml solution for infusion 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 Nicardipine Aguettant 1mg/ml solution for infusion. 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).

Table 3: List of important risks and missing information

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

II.B Summary of important risks

None

II.C Post-authorisation development plan

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

There is no study which is condition of the marketing authorisation or specific obligation of Nicardipine Aguettant 1mg/ml solution for infusion.

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

There is no study required for Nicardipine Aguettant 1mg/ml solution for infusion.