Part VI: Summary of the risk management plan

Summary of risk management plan for Nipruss® (Sodium nitroprusside)

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

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

I. The medicine and what it is used for

Nipruss® is authorised for treatment of Hypertensive Crisis and Induced Hypotension during surgery, respectively (see SmPC for the full indication). It contains Sodium nitroprusside as the active substance and it is given by intravenous infusion.

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

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

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

II.A List of important risks and missing information

Important risks of Nipruss® 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 Nipruss®. 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.

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

Nipruss® has neither any important identified nor important potential risk.

There is no missing information.

II.B Summary of important risks

Not applicable. 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

There are no studies being conditions of the marketing authorisation or specific obligation of Nipruss®.

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

There are no studies required for Nipruss®.