PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Suprane 100% inhalation vapour, liquid (desflurane)

This is a summary of the Risk Management Plan (RMP) for Suprane 100% inhalation vapour, liquid (hereafter Suprane). The RMP provides details on the important risks of Suprane, how these risks can be minimized, and how more information will be obtained about Suprane's risks and uncertainties (missing information).

The Summary of Product Characteristics (SmPC) and Package Leaflet (PL) for Suprane provide essential information to healthcare professionals and patients on how Suprane should be used.

New safety concerns and/or changes to the current safety concerns will be included in future updates of the RMP.

I. The medicine and what it is used for

Suprane is indicated as an inhalation agent for maintenance of general anesthesia for inpatient and outpatient surgery in adults, adolescents and intubated infants and children. It contains desflurane 100% as the active substance, and it is given by inhalation.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Suprane, together with measures to minimize such risks and the proposed studies for learning more about Suprane's risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorized pack size – the amount of medicine in a pack is chosen so as 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).

Together, these measures constitute *routine risk minimization measures*.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including periodic safety update report (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 Suprane are risks that need special risk management activities to further investigate or minimize 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 Suprane. 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).

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

II.B Summary of important risks and missing information

There are no safety concerns included in this RMP. All risks associated with the use of Suprane are considered fully characterized and appropriately managed with routine risk minimization measures in the product information which are fully integrated into standard clinical practice.

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligations of Suprane.

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

There are no studies required for Suprane.