PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Brevibloc (esmolol hydrochloride)

This is a summary of the Risk Management Plan (RMP) for Brevibloc. The RMP details important risks of Brevibloc, how these risks can be minimized, and how more information will be obtained about Brevibloc's risks and uncertainties (missing information).

Brevibloc's Summary of Product Characteristics (SmPC) and its Package Leaflet (PL) give essential information to healthcare professionals and patients on how Brevibloc should be used.

Important new safety concerns or changes to the current ones will be included in updates of Brevibloc's RMP.

I. The medicine and what it is used for

Brevibloc is authorized for supraventricular tachycardia (except for pre-excitation syndromes), non-compensatory sinus tachycardia, and tachycardia and hypertension occurring in the perioperative phase (refer to the SmPC for the full indication). It contains esmolol hydrochloride as the active substance, and it is given by intravenous administration.

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

Important risks of Brevibloc; together with measures to minimize such risks and the proposed studies for learning more about Brevibloc'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) can help to minimize its risks.

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 Brevibloc 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 Brevibloc. 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

Not applicable.

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 Brevibloc.

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

There are no studies required for Brevibloc.