Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for 'Midazolam B. Braun 1 mg/ml and 5 mg/ml, Solution for Injection/Infusion' (Midazolam B. Braun [Midazolam])

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

'Midazolam B. Braun's' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how 'Midazolam B. Braun' should be used.

I. The Medicine and What it is Used for

'Midazolam B. Braun' is a short-acting medicine that is used to induce sedation (a very relaxed state of calm, drowsiness or sleep) and relieves anxiety and muscle tension and is authorised for:

- conscious sedation (an awake but very relaxed state of calm or drowsiness) during a medical test or procedure in adults and children,
- sedation of adults and children, in intensive care units,
- anaesthesia in adults, used alone or with other medicines,
- premedication (to cause relaxation, calm and drowsiness before an anaesthetic) in adults and children.

It contains midazolam, belongs to a group of substances called benzodiazepines, as the active substance and it is given by intravenous (i.v.), intramuscular (i.m.) route of administration.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of 'Midazolam B. Braun', together with measures to minimise such risks and the proposed studies for learning more about 'Midazolam B. Braun'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 PL 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 are regularly analysed, 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 'Midazolam B. Braun' 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 'Midazolam B. Braun'. 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 yet been established 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.

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, as there are no important risks for 'Midazolam B. Braun'.

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 'Midazolam B. Braun'.

II.C.2 Other Studies in Post-authorisation Development Plan

There are no studies required for 'Midazolam B. Braun'.