PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

This is a summary of the risk management plan (RMP) for CARBETOCIN 100 micrograms solution for injection in pre-filled syringe (CARBETOCIN). The RMP details important risks of CARBETOCIN, how these risks can be minimised, and how more information will be obtained about CARBETOCIN's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

CARBETOCIN is authorised for the prevention of postpartum haemorrhage due to uterine atony. It contains carbetocin as the active substance and it is given by solution for injection in pre-filled syringe as follows:

Caesarean section under epidural or spinal anaesthesia:
Inject 1 ml of CARBETOCIN containing 100 micrograms carbetocin and administer only by intravenous injection, under adequate medical supervision in a hospital.

Vaginal delivery:
Inject 1 ml of CARBETOCIN containing 100 micrograms carbetocin and administer by intravenous injection or intramuscular injection, under adequate medical supervision in a hospital.

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

Important risks of CARBETOCIN, together with measures to minimise such risks and the proposed studies for learning more about CARBETOCIN'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 (i.e., hospital use only) 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, 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 CARBETOCIN solution for injection 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 CARBETOCIN. 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	• Cardiac arrhythmias
Missing information	• None

II.B Summary of important risks

The safety information in the product information is aligned to the reference medicinal product.

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 authorisation, or specific obligation for CARBETOCIN.

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

There are no studies required for CARBETOCIN.