Summary of Risk Management Plan

for carbetocin

Active substance(s) (INN or common name):	Carbetocin
Product(s) concerned (brand name(s)):	PABAL CARBETOCIN FERRING
Name of Marketing Authorisation Holder or Applicant:	Ferring AG Baarermatte 6340 Baar Switzerland
RMP version	1.1

Disclaimer:

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Ferring carbetocin is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Ferring carbetocin in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Ferring AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Ferring Carbetocin.

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Part VI: Summary of the risk management plan

Summary of risk management plan for DURATOBAL, DURATOCIN, LONACTENE, PABAL, CARBETOCIN FERRING (carbetocin). In the below the tradename PABAL will be used to cover for all tradenames of Ferring's carbetocin.

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

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

I. The medicine and what it is used for

PABAL is authorised for prevention of uterine atony and excessive bleeding following delivery of the infant by Caesarean section (CS) under epidural or spinal anaesthesia (see SmPC for the full indication) and proposed for prevention of uterine atony following vaginal delivery. It contains carbetocin as the active substance and it is given by intramuscular or intravenous route of administration.

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

Important risks of PABAL, together with measures to minimise such risks and the proposed studies for learning more about PABAL'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 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 PABAL is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of PABAL 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 PABAL. 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;

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

Important potential risk Cardiac arrhythmias	
Evidence for linking the risk to the medicine	Isolated postmarketing reports have been seen, however these are of poor strength due to confounders such as anaesthesia, concomitant medication and the surgical procedure in itself.
Risk factors and risk groups	Carbetocin should be used with caution in patients who have a pre-disposition to myocardial ischemia due to pre-existing cardiovascular disease (such as hypertrophic cardiomyopathy, valvular heart disease and/or ischemic heart disease) to avoid significant changes in blood pressure and heart rate in these patients.

Risk minimisation measures	Routine risk communication: SmPC section 4.2 and 4.4 specifies recommendation of carbetocin administration slowly over 1 minute when administered intravenous. SmPC section 4.3 states that serious cardiovascular disorders are a contraindication to the use of carbetocin and PL section 2 instructs not to use carbetocin if the patient has serious heart disease. SmPC section 4.4 warns that carbetocin must only be administered at well-equipped specialist obstetrics units, and that carbetocin must be used cautiously in the presence of cardiovascular disease. PL section 2 instructs the patient to inform doctor, midwife or nurse in case of heart or circulation problems. Additional risk minimisation measures: No additional risk minimisation measures

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 carbetocin.

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

There are no studies required for carbetocin.