IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Carbetocin EVER Pharma 100 micrograms/ml solution for injection
Carbetocin
PA1774/012/001

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the medicinal product for marketing in Ireland.

CONTENTS

I. INTRODUCTION

II. QUALITY ASPECTS

III. NON-CLINICAL ASPECTS

IV. CLINICAL ASPECTS

V. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

VI. REVISION DATE

VII. UPDATE

I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Carbetocin EVER Pharma 100 micrograms/mL solution for injection, from EVER Valinject GmbH on the 21/08/2026 for the prevention of postpartum haemorrhage due to uterine atony.

This application for a marketing authorisation was submitted in accordance with Article 10(1) of Directive 2001/83/EC, a so-called generic application. This was a decentralised procedure with Ireland as the reference member state.

The Summary of Product Characteristics for (SmPC) for this medicinal product is available on the HPRA's website at https://www.hpra.ie/find-a-medicine/for-human-use/authorised-medicines.

Name of the product	**Carbetocin EVER Pharma**
Name(s) of the active substance(s) (INN)	**Carbetocin**
Pharmacotherapeutic classification (ATC code)	**H01BB03**
Pharmaceutical form and strength(s)	**100 micrograms/ml Solution for injection**
Marketing Authorisation Number(s) in Ireland	**PA1774/012/001**
Marketing Authorisation Holder	**EVER Valinject GmbH**
MRP/DCP No.	**IE/H/1358/001/DC**
Reference Member State IE	**IE**
Concerned Member State	**AT,BE,BG,CZ,DE,DK,EE,EL,ES,FI,FR,HR,HU,IT,LT,** LV,NL,NO,PL,PT,RO,SE,SI,SK

II. QUALITY ASPECTS

II.1. Introduction

This application is for Carbetocin EVER Pharma 100 micrograms/mL solution for injection.

II.2 Drug substance

The active substance is carbetocin, an established active substance, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

The active substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

The drug product consists of 100 micrograms of carbetocin per 1 mL of aqueous solution. Presentations are as 100 micrograms/mL in 1 mL ampoules, or 2R vials (2 mL).

The excipients in the medicinal product are listed in section 6.1 of the SmPC.
A visual description of the product is included in section 3 of the SmPC.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form (solution for injection) and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to the relevant European and ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients/*Ancillary Substances*)

All ingredients comply with Ph. Eur. or are adequately controlled by the manufacturer's specifications.

P.5/6 Control of Finished Product

The Finished Product Specification is based on the Ph. Eur. monograph for solutions for injection, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by adequate validation data.

Batch analytical data for a number of batches from the proposed production site(s) have been provided and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.7 Packaging material

The approved packaging for this product is described in section 6.5 of the SmPC.

Evidence has been provided that the packaging complies with Ph. Eur. and EU legislative requirements.

P.8 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects
The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Carbetocin EVER Pharma 100 micrograms/mL solution for injection.

III. NON-CLINICAL ASPECTS

III.1 Introduction
This active substance is a generic formulation of Carbetocin EVER Pharma 100 micrograms/mL solution for injection on the European market. No new preclinical data have been submitted. This is acceptable for this type of application.

The pharmacodynamic, pharmacokinetic and toxicological properties of carbetocin are well known.

III.2 Pharmacology

III.3 Pharmacokinetics

III.4 Toxicology

No new data were submitted and none were required for this application. A clinical overview based on literature review was provided and is acceptable. Non-clinical findings are adequately represented in the appropriate sections of the SmPC.

III.5 Ecotoxicity/environmental risk assessment

The active substance is a non-natural peptide/protein and it is excreted by humans in amounts < 1 % of the dose. The use of carbetocin will not alter the concentration or distribution of the substance in the environment. Therefore, carbetocin is not expected to pose a risk to the environment.

III.6 Discussion on the non-clinical aspects

The pharmacodynamic, pharmacokinetic and toxicological properties of carbetocin are well known. As carbetocin is a widely used, well-known active substance, the applicant has not provided additional studies, and further studies are not required. A nonclinical overview based on literature review was provided and is acceptable. Non-clinical findings are adequately represented in the appropriate sections of the SmPC.

CLINICAL ASPECTS

IV.1 Introduction

Carbetocin is a well known active substance with established efficacy and tolerability.

The content of the SmPC approved during the decentralised procedure is in accordance with that accepted for the reference product Pabal marketed by Ferring Ireland Ltd.

For this generic application, as this is an aqueous parenteral solution of equivalent strength to the reference, no bioequivalence study was submitted and none was required.

The HPRA has been assured that GCP standards were followed in an appropriate manner in the studies conducted.

IV.2 Pharmacokinetics, Pharmacodynamics, Clinical Efficacy, Clinical Safety

The pharmacodynamic, pharmacokinetic and clinical safety/efficacy properties of carbetocin are well known. As carbetocin is a widely used, well-known active substance, the applicant has not provided additional studies, and further studies are not required. A clinical overview based on literature review was provided and is acceptable. Clinical findings are adequately represented in the appropriate sections of the SmPC.

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Carbetocin EVER Pharma 100 micrograms/ml solution for injection.

Summary of Safety Concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

Routine pharmacovigilance and risk minimisation activities are sufficient to identify, characterise, prevent or minimise risks relating to Carbetocin EVER Pharma 100 micrograms/ml solution for injection.

PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

IV.6 Discussion on the clinical aspects

All clinical aspects of the application are considered to be fully acceptable, in line with the rationale outlined above.

IV. CLINICAL ASPECTS

IV.1 Introduction

Carbetocin is a well known active substance with established efficacy and tolerability.

The content of the SmPC approved during the decentralised procedure is in accordance with that accepted for the reference product Pabal marketed by Ferring Ireland Ltd.

For this generic application, as this is an aqueous parenteral solution of equivalent strength to the reference, no bioequivalence study was submitted and none was required.

The HPRA has been assured that GCP standards were followed in an appropriate manner in the studies conducted.

IV.2 Pharmacokinetics, Pharmacodynamics, Clinical Efficacy, Clinical Safety

The pharmacodynamic, pharmacokinetic and clinical safety/efficacy properties of carbetocin are well known. As carbetocin is a widely used, well-known active substance, the applicant has not provided additional studies, and further studies are not required. A clinical overview based on literature review was provided and is acceptable. Clinical findings are adequately represented in the appropriate sections of the SmPC.

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Carbetocin EVER Pharma 100 micrograms/ml solution for injection.

Summary of Safety Concerns	
Important identified risks	None
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Missing information	None

Routine pharmacovigilance and risk minimisation activities are sufficient to identify, characterise, prevent or minimise risks relating to Carbetocin EVER Pharma 100 micrograms/ml solution for injection.

PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

IV.6 Discussion on the clinical aspects

All clinical aspects of the application are considered to be fully acceptable, in line with the rationale outlined above.

V. OVERALL CONCLUSIONS

Carbetocin EVER Pharma 100 micrograms/mL solution for injection is a generic form of Pabal solution for injection, which is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

As this is an aqueous parenteral solution of equivalent strength to the reference, no bioequivalence study was submitted and none was required, this is in compliance with the CHMP guidance documents. The SmPC is consistent with that of the reference product.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The HPRA, on the basis of the data submitted considered that Carbetocin EVER Pharma 100 micrograms/mL solution for injection is bioequivalent with the reference product as well as a satisfactory risk/benefit profile and therefore granted a marketing authorisation.

VI. REVISION DATE

20/08/2031