LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Carboprost Alembic
(carboprost trometamol)

SE/H/2389/01/DC

This module reflects the scientific discussion for the approval of Carboprost Alembic. The procedure was finalised on 2025-07-15. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, a marketing authorisation has been granted for Carboprost Alembic, 0,25 mg/ml, Solution for injection.

The active substance is carboprost trometamol, carboprost. A comprehensive description of the indication and posology is given in the SmPC.

For recommendations to the marketing authorisation not falling under Article 21a/22a/22 of Directive 2001/83/EC and conditions to the marketing authorisation pursuant to Article 21a/22a/ 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

The application for Carboprost Alembic, 0,25 mg/ml, solution for injection, is a generic application submitted according to Article 10(1) of Directive 2001/83/EC. The applicant applies through the Decentralised Procedure with Sweden acting as reference member state (RMS) and MT as concerned member state (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Prostinfenem, 0.25 mg/ml, solution for injection, form authorised in SE since 1985, with Pfizer AB as marketing authorisation holder.

European Reference Product (ERP)
A European Reference Product is used in CMS MT: Prostinfenem, 0.25 mg/ml, solution for injection, authorised in SE since 1985, with Pfizer AB as marketing authorisation holder.
The justification to use this product is based on RMS's own files. The ERP information was circulated by RMS during the validation period.

Potential similarity with orphan medicinal products
Not applicable

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III. NON-CLINICAL ASPECTS

Pharmacology/Pharmacokinetics/Toxicology
Pharmacodynamic, pharmacokinetic and toxicological properties of carboprost trometamol are well known. As carboprost trometamol is a widely used, well-known active substance, no further studies are required and the applicant provides none. Overview based on literature review is, thus, appropriate.

Environmental Risk Assessment (ERA)
Since Carboprost Alembic is a generic product, it will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

There are no objections to approval of Carboprost Alembic from a non-clinical point of view.

IV. CLINICAL ASPECTS

Pharmacokinetics
The applicant has not submitted any bioequivalence studies. Absence of bioequivalence studies is acceptable. Since the product applied for is to be administered as an aqueous intramuscular solution containing the same active substance and the same excipients in similar amounts as the currently authorised product, no bioequivalence study is required according to the Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1). There are no objections to approval of Carboprost Alembic 0.25 mg/ml, solution for injection from a pharmacokinetic point of view.

Pharmacodynamics/Clinical efficacy/Clinical safety
No bioequivalence study is needed for this injectable product.

No new studies on pharmacodynamics, clinical efficacy or clinical safety have been submitted which is considered acceptable for a generic product. In support of the application a Clinical Overview has been submitted which adequately summarizes the clinical background supporting the indication postpartum haemorrhage. An updated Clinical Overview has been provided to support of the indication termination of pathological pregnancy.

Risk Management Plan
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 Carboprost Alembic.

Safety specification
The current application is a generic version of an already authorised reference product. Reference is therefore made to the pre-clinical and clinical data obtained by the manufacturer of the reference product during the exclusivity period. This information has already been incorporated in the Summary of Product Characteristics and the package leaflet included in eCTD module 1.3.

The active substance, Carboprost Tromethamine Injection, 0.25 mg/ml have been widely used throughout Europe since 1985 and as such the reference product ‘Prostinfenem’ as authorized by EMA,

does not operate any risk management systems. Till date there are no safety concern requiring additional risk minimization activities identified with the reference medicinal product. Accordingly, only routine pharmacovigilance activities are considered necessary for Post-authorization safety monitoring of this product.

Pharmacovigilance Plan
The Pharmacovigilance System Master File (PSMF) for Alembic is in place and Alembic Pharmaceuticals Europe Ltd commits to keep it updated at all times. The objective of the pharmacovigilance strategy is to systematically collect adverse drug reactions (ADRs) from multiple sources and to conduct real time and periodic medical assessments of single and aggregate cases to identify potential safety signals. Early detection of safety signals enables the marketing authorisation (MA) to develop and implement an appropriate risk management strategy. The objective of the routine surveillance program conducted by the MA holder is to systematically review safety data from multiple sources. The purpose of surveillance is to detect and evaluate changes in reporting frequency of adverse events (AEs) and changes in overall AE pattern suggestive of potential new safety concerns.

Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures
Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

Summary of the RMP
The submitted Risk Management Plan, version 0.0 signed 03-Feb-2023 is considered acceptable.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

V. USER CONSULTATION

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PL was English.

The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Carboprost Alembic, is found adequate. There are no objections to approval of Carboprost Alembic, from a non-clinical and clinical point of view. The absence of bioequivalence studies is acceptable. The product information is acceptable. The benefit/risk is considered positive, and the application is therefore recommended for approval.

List of recommendations not falling under Article 21a/22a/22 of Directive 2001/83/EC in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a/22a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

The decentralised procedure for Carboprost Alembic, 0,25 mg/ml, Solution for injection was positively finalised on 2025-07-15.

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Public Assessment Report – Update

Procedure number*	Scope	Product Information affected (Yes/No)	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

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