Institute for State Control of Veterinary Biologicals and Medicines
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Czech Republic
(Reference Member State)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

KARBETOCIN BIOVETA 0.07 mg/ml solution for injection

PRODUCT SUMMARY

EU procedure number	CZ/V/0205/001/DC
Name, strength and pharmaceutical form	Karbetocin Bioveta 0.07 mg/ml solution for injection
Applicant	Bioveta, a.s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic
Active substance(s)	Carbetocin
ATC vet code	QH01BB03
Target species	Cattle, pigs
Indication for use	Reproductive system

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	LongActon 0,07 mg/ml
Marketing authorisation holder	Vetoquinol S.A.
MS where the RP is or has been authorised	Germany
Marketing authorisation number	400323.00.00
EU procedure number	DE/V/0106/001
Date of authorisation	22/02/2000
Date of completion of the original decentralised procedure	29/10/2025
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	N.A.
Concerned Member States for original procedure	BG-EE-HU-LT-LV-PL-RO
Concerned Member States for subsequent recognition procedure	N.A.
Withdrawn CMS during original decentralised procedure	N.A.

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species.

The VMP is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contains 0.07 mg/ml of carbetocin as the active substance and the excipients chlorobutanol hemihydrate, acetic acid glacial, sodium acetate trihydrate and water for injections.

The container/closure system consists of clear colourless glass vials of hydrolytic class I, closed with a bromobutyl rubber stopper and sealed with a flip-off aluminium cap. The authorised package sizes are 1 x 10 ml and 1 x 50 ml. Vials are inserted into a carton box

The VMP is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Description of the manufacturing method

The VMP is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation for full-scale batches will be performed post-authorisation.

C. Production and control of starting materials

The active substance carbetocin is an established active substance which is not described in the European Pharmacopeia and thus it is controlled by an in-house specification. Scientific data have been provided using the ASMF.

The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

The product contains the excipients chlorobutanol hemihydrate, acetic acid glacial, sodium acetate trihydrate and water for injections which are described in Ph. Eur. monographs and are controlled accordingly.

Quality control of the container-closure system is described and considered adequate.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this VMP.

D. Control tests carried out on isolated intermediates during the manufacturing process

Not applicable.

E. Control tests on the finished product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification and their limits have been justified and are considered appropriate to adequately control the quality of the VMP.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification.

F. Stability tests

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf-life when stored under the approved conditions. The in-use shelf-life of the product is supported by relevant data.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of toxicological tests are not required. The user safety aspects of this VMP is/are identical to the reference VMP. Updated warnings and precautions as listed on the product literature are adequate to ensure safety of the product to users / the environment / consumers.

A. Safety tests

User safety

The applicant has provided a user safety assessment and warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 as a generic application. An environmental risk assessment (ERA phase II) has not been provided. This approach was accepted, because according to the Reflection paper on the interpretation of Article 18(7) of Regulation (EU) 2019/6 (EMA/CVMP/ERA/622045/2020), no

ERA phase II is required as product is intended to be used to treat a small number of animals in herd.
No specific toxicity was addressed in the product literature and no risk mitigation measures have been implemented.

B. Residues documentation

Residue tests

This application has been submitted in accordance with Article 18 of Regulation (EU) 2019/6 as a generic application, and essential similarity to a reference VMP has been demonstrated. No own residue depletion studies were conducted.

Maximum Residue Limits

The active substance carbetocin is included in the list of allowed substances as described in Table 1 of the Annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance(s)	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Carbetocin	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY

The excipients (acetic acid, sodium acetate trihydrate) are included in the category of the food additives in the Table 1 of the Annex to Commission Regulation (EU) No 37/2010 and water is included in the list substances considered as not falling within the scope of Regulation (EC) No. 470/2009.

Withdrawal Periods

Based on the data provided above, the following text of the withdrawal periods are included in the product information:

Cattle, pigs: Meat and offal: Zero days.
Cattle: Milk: Zero hours.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

No pre-clinical studies were performed.

B. Clinical trials

No clinical trials were performed.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which have been made after the original procedure, which are important for the quality, safety or efficacy of the VMP.

None.