Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Novocillin LC

Date: rev. 13.
January 2022

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0333/001/DC
Name, strength and pharmaceutical form	Novocillin LC intramammary suspension for lactating cows
Applicant	Pharmanovo Veterinärarzneimittel GmbH Liebochstrasse 9 A-8143 Dobl
Active substance(s)	Oxacillin sodium 1000mg
ATC Vetcode	QJ51CF04
Target species	Cattle (lactating cows)
Indication for use	Treatment of clinical mastitis caused by *Staphylococci spp*. (including β-lactamase producing strains) and *Streptococci spp.* susceptible to oxacillin.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	23 September 2020
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure Repeat Use CMS	AT, CY, CZ, ES, FR, HU, IS, LT, PL, PT BG, EE, IE, IT, RO, UK(NI)

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; any reactions observed are indicated in the SPC.
The product 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 safety and efficacy aspects of this product are identical to the reference product Oxacillin-Na 1000 mg Euter-Injektor authorised in Germany in 2003. The initial application for the reference product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

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

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains the active substance oxacillin sodium (1000 mg) as oxacillin sodium monohydrate and the excipients white soft paraffin and medium-chain triglycerides.

The container/closure system is a 10 g intramammary syringe with plunger and cap made of linear low-density polyethylene (LLDPE).

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

B. Method of Preparation of the Product

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

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is oxacillin sodium monohydrate, an established substance described in the European Pharmacopoeia. 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.

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

D. Control on intermediate products

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 product.

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

Stability data on the active substance has 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 product throughout its shelf life when stored under the approved conditions.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological studies are not required.
The applicant has provided a user safety assessment in compliance with the relevant guideline. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

Phase I:
The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the initial predicted environmental concentration in soil (PECsoil) is less than 100 µg/kg.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted by the applicant as this is a generic application according Article 13 (3) of Directive 2001/82/EC (as amended).

MRLs

Oxacillin is listed in Table 1 of the Annex of Commission Regulation (EU) No. 37/2010:

Pharmacologically active Substance	Marker residue	Animal Species	MRL	Target Tissues	Other Provisions	Therapeutic Classification
Oxacillin	Oxacillin	All food producing species	300 µg/kg 300 µg/kg 300 µg/kg 300 µg/kg 30 µg/kg	Muscle Fat Liver Kidney Milk	For fin fish the muscle MRL relates to 'muscle and skin in natural proportions'. MRLs for fat, liver and kidney do not apply to fin fish. For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportions'. Not for use in animals from which eggs are produced for human consumption.	Anti-infectious agents/Antibiotics

Withdrawal Periods

Based on the generic nature of the application, the following withdrawal periods for cattle are justified and considered safe to ensure consumer safety:

Meat and offal: 6 days
Milk: 144 hours (6 days)

IV. CLINICAL ASSESSMENT (EFFICACY)

This is a generic application according to Article 13(3) of Directive 2001/82/EC as amended, and bioequivalence with a reference product has been demonstrated, in accordance with section 7.1.d of the Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMEA/CVMP/016/00-Rev.3).
Therefore, efficacy and target animal safety studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13(3), no target animal tolerance studies were conducted.
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

Resistance

The bibliography information provided, suggests that there are no concerns on resistances for Oxacillin.
Adequate warnings and precautions appear on the product literature.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product 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 product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

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 product.

Summary of change **(Application number)**	**Section updated in Module**	**Approval date**
Including Vet-Agro Multi-Trade Company Sp. z o.o. as additional manufacturer for batch control/testing, batch release and secondary packaging **Change in pack size of the finished product:** **- Addition of a pack size of 24 intramammary syringes containing 10 g suspension each** **DE/V/0333/IB/001/G**	**Module 4**	**13 January 2022**