College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board Agency

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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

BOVIX MICROCLOX EDC, 600 mg Intramammary Suspension

Cloxacillin

NL/V/0416/001/DC

CREATED: May 2026

PRODUCT SUMMARY

EU procedure number	NL/V/0416/001/DC
Name, strength and pharmaceutical form	BOVIX MICROCLOX EDC, 600 mg Intramammary Suspension
Applicant	Kernfarm B.V. De Corridor 14D 3621 ZB Breukelen The Netherlands
Active substance(s)	Cloxacillin
ATC vetcode	QJ51CF02
Target species	Cattle (dairy cow at drying-off)
Indication for use	For the treatment of subclinical mastitis at drying off caused by *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis, Staphylococcus aureus* and *Trueperella pyogenes*.

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*	Hybrid application in accordance with Article 19 of Regulation (EC) 2019/6 as amended.
Reference product (RP)	ORBENIN EXTRA DRY COW, 600 mg suspensie voor intramammair gebruik voor runderen
Marketing authorisation holder	Zoetis B.V
MS where the RP is or has been authorised	NL
Marketing authorisation number EU procedure number	REG NL 6901
Date of authorisation	09 November 1989
Date of completion of the decentralised procedure	27 November 2024
Concerned Member States for original procedure	BE, DE, ES, FR, IT, PL
Concerned Member States for subsequent recognition 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 600 mg of Cloxacillin base (as Cloxacillin benzathine) per 3.6 g syringe and the following excipients: liquid paraffin, aluminium stearate and stearic acid.

The bulk product is packed in LDPE injectors.

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

A waiver is claimed based on physico-chemical equivalence with the reference product.

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.

The VMP is manufactured using conventional manufacturing techniques. However, pre-approval validation results on three production batches have been provided.

The validation of the maximum holding is adequate.

The tests performed during production are described.

C. Production and control of starting materials

The active substance Cloxacillin benzathine is an established active substance described in the BP Vet Pharmacopoeia.

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

An ASMF procedure has been employed and no concerns were raised.

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.

All excipients are in conformity with the Ph.Eur. requirements.

The packaging is conformity with the Ph. Eur. and EU Food Directive.

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.

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.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and pharmaceutical equivalence with the reference product has been established, results of safety tests are not required

The safety aspects of this VMP are identical to the reference VMP.

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

Pharmacological studies

Not required.

Toxicological studies

Not required.

Observations in humans

Not required.

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. A risk was identified with respect to hypersensitivity reactions.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

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

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, initial = 18.13 µg/kg) is less than 100 µg/kg.

B. Residues documentation

Residue tests

No residue depletion studies were conducted because this is a hybrid application submitted according to Article 19 of Regulation (EC) No 2019/6, and pharmaceutical equivalence with the reference product has been established.

Maximum Residue Limits

Cloxacillin is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	**Marker residue**	**Animal Species**	**MRL**	**Target tissues**	**Other provision**	**Therapeutic Classification**
Cloxacillin	Cloxacillin	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	Anti-infectious agents/ Chemotherapeutics

					fin fish. For porcine and poultry species the fat MRL relates to 'skin and fat in natural proportion s'.	

The excipients are allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required when used as in this product.

Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:

Meat and offal: zero days.
Milk:
- if calving occurs at least 42 days after treatment: 48 hours post calving.
- if calving occurs less than 42 days after treatment: 44 days after last treatment.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and pharmaceutical equivalence with the reference product has been established, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

A. Pre-Clinical Studies

Pharmacology

As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and pharmaceutical equivalence with the reference product has been established, no results of pharmacology studies were provided.

Development of resistance and related risk in animals

Adequate warnings and precautions appear on the product literature in accordance with the 'Revised guideline on the SPC for antimicrobial products'.

Dose determination and confirmation

Not required.

Tolerance in the target species of animals

Not required.

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.