AGENCE NATIONALE DU
MEDICAMENT VETERINAIRE

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Bimacure 500 mg Intrauterine Suspension for Cattle

DATE: 01/08/2022

French agency for food, environnemental and occupational health safety– French Agency for Veterinary Medicinal Products
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MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0419/001/DC
Name, strength and pharmaceutical form	Bimacure 500 mg Intrauterine Suspension for Cattle
Applicant	Bimeda Animal Health Limited Unit 2, 3 & 4 Airton Close, Tallaght Dublin 24, IRELAND
Active substance(s)	Cefapirin (as cefapirin benzathine)
ATC Vetcode	QG51AA05
Target species	Cattle (cows)
Indication for use	For the treatment of clinical endometritis in cows (at least 21 days after parturition) caused by *Trueperella pyogenes, Prevotella spp.* (formerly *Bacteroides spp.*) and *Fusobacterium necrophorum*.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website https://www.anses.fr/en/thematique/veterinary-medicine-anmv

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Article 13(3) hybrid application of Directive 2001/82/EC as amended
Date of completion of the original decentralised procedure	29 June 2022
Concerned Member States for original procedure	AT, DE, EE, ES, IE, IT, LT, LV, PL

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.
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 efficacy of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Composition

The product contains 0.5 g of cefapirin (as benzathine) per 19.0 g syringe and the following excipients: castor oil hydrogenated, macrogol cetostearyl ether 12, macrogol cetostearyl ether 20 and triglycerides medium chain.
The packaging of the finished product is as described on the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.
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 from 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 cefapirin benzathine, an established active substance. 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

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

E. Control on intermediate products

Not applicable.

F. 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.

G. Stability

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 product throughout its shelf life when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

The application has been submitted according to Article 13(3) of Directive 2001/82/EC as amended. The cited reference product is METRICURE (INTERVET) authorized in France in 1996.

III.A Safety Testing

Pharmacological Studies

As this is an application according to Article 13(3), and bioequivalence with the reference product has been accepted, results of pharmacological studies are not required.

Toxicological Studies

As this is an application according to Article 13(3), and bioequivalence with the reference product has been accepted, results of toxicological studies are not required.

User Safety

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

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted as bioequivalence of the product and the reference product was demonstrated.

MRLs

The active substance, cefapirin, is included in table 1 of the MRL regulation 37/2010, as follows:

CEFAPIRIN						
Marker residue	**Animal Species**	**MRL**	**Target Tissues**	**Other Provisions**	**Therapeutic Classification**	**Regulation**
Sum of cefapirin and desacetylcefapirin	Bovine	50 µg/kg 50 µg/kg 100 µg/kg 60 µg/kg	Muscle Fat Kidney Milk	No entry	Anti-infectious agents/ Antibiotics	37/2010 of 22.12.2009

Withdrawal Periods

The same withdrawal periods as for the reference product are applicable.

Species	Tissues	Withdrawal periods
Bovine	Meat & offal	2 days
	Milk	0 days

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacological Studies

As this is an application according to Article 13(3), and bioequivalence with the reference product has been accepted, results of pharmacological studies are not required.

Tolerance in the Target Species of Animals

As this is an application according to Article 13(3), and bioequivalence with the reference product has been accepted, results of tolerance studies are not required.

Resistance

Adequate warnings and precautions appear on the product literature.

IV.B Clinical Studies

As this is a hybrid application according to paragraph 3 of Article 13 of Directive 2001/82/EC, as amended, and bioequivalence with the reference product has been accepted, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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.