BIMACURE

500 mg Intrauterine Suspension for Cattle

DATA SHEET

INDICATIONS 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*.

BENEFITS

- Excellent syringability for ease of administration
- Responsible use- first generation cephalosporin
- Efficacy- broad spectrum
- 1st generic cefapirin intrauterine suspension marketed in Ireland.

LIST No	UNIT PACKAGE	CASE SIZE
1BIM000	10 Syringes	1

See reverse for Administration & Dosage

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QUALITATIVE AND QUANTITATIVE COMPOSITION

Each syringe contains:

Active substance:

Cefapirin 500 mg
(as Cefapirin benzathine)

Excipients:

Qualitative composition of excipients and other constituents
Macrogol cetostearyl ether-20
Macrogol cetostearyl ether-12
Hydrogenated castor oil
Triglycerides, medium chain

Off-white to cream oily intrauterine suspension.

CLINICAL INFORMATION

TARGET SPECIES

Cattle (cows).

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CONTRAINDICATIONS

Do not use in cases of hypersensitivity to cephalosporins, other β-lactam antibiotics or to any of the excipients.

SPECIAL WARNINGS

Cross-resistance has been shown between cefapirin and others betalactams. Use of the product should be carefully considered when susceptibility testing has shown resistance to others betalactams because its effectiveness may be reduced.

SPECIAL PRECAUTIONS FOR USE

Special precautions for safe use in the target species:

Use of the veterinary medicinal product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level. Use of the veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies. An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach. Narrow spectrum antibiotic therapy with a lower risk of antimicrobial resistance selection should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Respect the usual conditions of asepsis. Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this veterinary medicinal product if you know you are sensitised to penicillins or cephalosporins or if you have been advised not to work with such preparations. Handle this veterinary medicinal product with care to avoid exposure, taking all recommended precautions. Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

ADVERSE EVENTS

None.

Très rare (<1 animal / 10 000 animaux traités, y compris les cas isolés) :	Réaction d'hypersensibilité

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

USE DURING PREGNANCY, LACTATION OR LAY

Pregnancy and lactation:

The use is not recommended during pregnancy. Can be used during lactation. Laboratory studies in mice, rats, and hamsters have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Because no specific studies have been performed in the target animal species, use only according to the benefit/risk assessment by the responsible veterinarian in breeding animals.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Not to be administered concurrently with other intrauterine antibiotic preparations.

ADMINISTRATION ROUTES AND DOSAGE

For intrauterine use.

The contents of one syringe of the veterinary medicinal product, corresponding to 500 mg of cefapirin (as cefapirin benzathine) should be introduced into the lumen of the uterus using the disposable catheter provided as follows:

1. The product may settle but can be re-suspended by gentle shaking into a homogeneous suspension.
2. Fix the syringe to the catheter.
3. Take the cervix of the uterus into one gloved hand introduced into the rectum.
4. Introduce the catheter through the cervix into the lumen of the uterus, by gentle oscillating movements of the cervix.
5. Inject the veterinary medicinal product.

The effects of one single administration should be evaluated after one week. In case of insufficient results, a single repeat dose can be administered one week after the initial treatment.

SYMPTOMS OF OVERDOSE (AND WHERE APPLICABLE, EMERGENCY PROCEDURES AND ANTIDOTES)

None known.

SPECIAL RESTRICTIONS FOR USE AND SPECIAL CONDITIONS FOR USE, INCLUDING RESTRICTIONS ON THE USE OF ANTIMICROBIAL AND ANTIPARASITIC VETERINARY MEDICINAL PRODUCTS IN ORDER TO LIMIT THE RISK OF DEVELOPMENT OF RESISTANCE

Not applicable.

WITHDRAWAL PERIODS

Meat and offal: 2 days.
Milk: Zero hours.

PHARMACOLOGICAL INFORMATION

ATCVET CODE:

QG51AA05.

PHARMACODYNAMICS

Cefapirin, a first-generation cephalosporin, is a broad-spectrum antibiotic with bactericidal action against gram-positive and gram-negative bacteria. Cefapirin is more resistant to the action of β-lactamase enzymes than penicillins. The bactericidal activity of cefapirin results from the inhibition of cell wall synthesis via affinity for penicillin-binding proteins (PBPs). Resistance mechanisms to cephalosporin include reduced permeability of the cell wall, enzymatic inactivation and change of specific penicillin binding sites. In Gram-positive bacteria, the main cephalosporin resistance mechanism is through alteration of penicillin binding proteins. Resistance of Gram-negative bacteria resistance consist largely in the production of β-lactamases. Limited field data is available regarding the prevalence of cefapirin resistance in organisms causing endometritis. Resistance to cephalosporins has been identified in uterine Enterobacterales which carry the CTX-M gene conferring the ability to produce Extended Spectrum β-lactamase (ESBL) enzymes. Resistance to cefapirin has also been identified in uterine isolates of *Trueperella pyogenes* but the mechanism of resistance has not been determined. Cross-resistance may occur with others B-lactams due to structural similarities.

PHARMACOKINETICS

After intrauterine treatment systemic absorption is low, which is reflected by the low plasma levels of cefapirin observed shortly after treatment. Twenty-four hours after treatment, cefapirin levels in plasma are below detectable levels (0.01 µg/ml). High cefapirin concentrations are observed in endometrium. Cefapirin concentrations in endometrium can be observed up to 24 hours. The active is eliminated by the kidneys.

PHARMACEUTICAL PARTICULARS

5.1 MAJOR INCOMPATIBILITIES

Not applicable.

SHELF LIFE

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: use immediately.

SPECIAL PRECAUTIONS FOR STORAGE

This veterinary medicinal product does not require any special storage condition.

NATURE AND COMPOSITION OF IMMEDIATE PACKAGING

Low linear density polyethylene syringe barrel with low density polyethylene plunger and cap containing 19g of oily suspension. Intrauterine catheters and gloves are provided for administration.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM THE USE OF SUCH PRODUCTS

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited

MARKETING AUTHORISATION NUMBER(S)

VPA22033/074/001

DATE OF FIRST AUTHORISATION

19 August 2022

DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

24 November 2023

CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

TAKE TIME OBSERVE LABEL DIRECTIONS

www.bimeda.ie

Bimeda data sheet created: August 2025