SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimacure 500mg Intrauterine Suspension for Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each 19 g syringe contains:

Cefapirin	500 mg
(as Cefapirin benzathine)	

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intrauterine suspension.
A creamy, oily suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cows.

4.2 Indications for use, specifying the target species

For the treatment of subacute and chronic endometritis in cows (at least 14 days after parturition) caused by bacteria susceptible to cefapirin.

4.3 Contraindications

Do not use in in animals with known hypersensitivity to cephalosporins or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to cefapirin and may decrease the effectiveness of the treatment.

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

Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross reactions to cephalosporins and *vice versa*.
Allergic reactions to these substances are occasionally serious.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. 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 with breathing are more serious symptoms and require urgent medical attention.

Gloves should be worn in order to avoid skin contact during preparation and administration of the product.
Accidental spillage on the skin should be washed off immediately with soap and water.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions have been observed in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The product is not recommended for use during pregnancy but can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Not to be administered concurrently with other intrauterine antibiotic preparations.

4.9 Amounts to be administered and administration route

The contents of one syringe 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 contents of the syringe into the uterus.

Depending on the response, a second treatment 7-14 days later may be required in some cases if clinical signs persist.
In animals that have been inseminated the product may be used one day after insemination. In cases of pyometra, pre-treatment with prostaglandin is recommended in order to induce luteolysis and remove debris from the uterine cavity.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Product supplied as a single dose syringe therefore overdose unlikely to occur.

4.11 Withdrawal period(s)

Meat and offal: 1 day.
Milk: Zero hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinfectives and antiseptics for intrauterine use, antibacterials, cefapirin.
ATC-vet code: QG51AA05.

5.1 Pharmacodynamic properties

Cefapirin, a first-generation cephalosporin, is a broad-spectrum antibiotic with bactericidal action against gram-positive and gram-negative bacteria. Cefapirin is resistant to the action of penicillinase.

5.2 Pharmacokinetic particulars

After intra-uterine treatment systemic absorption is low, which is reflected by the low plasma levels of cefapirin observed shortly after treatment. High cefapirin concentrations are observed in endometrium.
Twelve hours after treatment, cefapirin levels in plasma are below detectable levels. Cefapirin concentrations in endometrium can be observed up to 24 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether-20
Macrogol cetostearyl ether-12
Hydrogenated castor oil
Triglycerides, medium chain

6.2 Major incompatibilities

None known.

6.3 Shelf life

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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions
Syringes are for single use only.

6.5 Nature and composition of immediate packaging

Low linear density polyethylene syringe barrel with low density polyethylene plunger and cap containing 19g of oily suspension, packed in boxes of 10 syringes. Intra-uterine catheters are provided for administration.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 50146/4045

9. DATE OF FIRST AUTHORISATION

15 June 2022

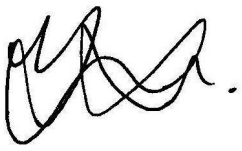
10. DATE OF REVISION OF THE TEXT

September 2022

PROHIBITION OF SALE, SUPPLY AND/OR USE

POM-V

To be supplied only on veterinary prescription.



Approved: 23 September 2022