ANNEX III

LABELLING AND PACKAGE LEAFLET

ANNEX III

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimacure 500mg Intrauterine Suspension for Cattle
Cefapirin (as Cefapirin benzathine)

2. STATEMENT OF ACTIVE SUBSTANCES

Each 19 g polyethylene syringe contains an oily suspension of 500 mg Cephapirin (as cephapirin benzathine).

3. PHARMACEUTICAL FORM

Intrauterine Suspension.

4. PACKAGE SIZE

10 syringes

5. TARGET SPECIES

Cows.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for directions, disposal advice and warnings before use.
Penicillin/cephalosporins may occasionally cause severe allergic reactions.

See package leaflet for user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4045

17. MANUFACTURER'S BATCH NUMBER

<Batch><Lot> {number}
Batch No:/Expiry end of:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimacure 500mg Intrauterine Suspension for Cattle
Cefapirin (as Cefapirin benzathine)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

500 mg cefapirin (as cefapirin benzathine).

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

19 g

4. ROUTE(S) OF ADMINISTRATION

Intrauterine.

5. WITHDRAWAL PERIOD(S)

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

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

<EXP {month/year}>
Expiry end of:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET: Bimacure 500mg Intrauterine Suspension for Cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Bimeda Animal Health Limited
Unit 2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bimacure 500mg Intrauterine Suspension for Cattle.
Cefapirin (as Cefapirin benzathine)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Syringe containing a suspension of 500 mg cefapirin (as Cefapirin benzathine) in an oily base**.**

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cows.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The contents of one syringe should be introduced into the lumen of the uterus using the disposable catheter provided as follows:

1. Shake syringe before use.
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 usedone 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.

9. ADVICE ON CORRECT ADMINISTRATION

Please see Section 8.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 1 day
Milk: Zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

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.

FOR ANIMAL TREATMENT ONLY.

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

Interaction with other medicinal products and other forms of interaction
Not to be administered concurrently with other intrauterine antibiotic preparations.

Overdose (symptoms, emergency procedures, antidotes):
Product supplied as a single dose syringe therefore overdose unlikely to occur.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

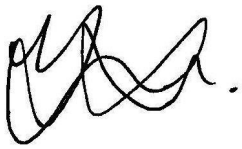
15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

Vm 50146/4045

PACKAGE QUANTITIES
Packs containing 10 syringes. Intrauterine catheters are provided for administration.



Approved: 23 September 2022