ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box/Polyethylene Bucket

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arentor DC 250mg Intramammary Suspension for Dry Cows

Cefalonium (as cefalonium dihydrate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each single dose 3g intramammary syringe contains 250mg Cefalonium (as cefalonium dihydrate)

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

20 intramammary syringes
120 intramammary syringes

5. TARGET SPECIES

Cattle (dry cows)

6. INDICATION(S)

***** Only for those Member States where space permits *****

For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Trueperella pyogenes*, *Escherichia coli* and *Klebsiella* spp. susceptible to cefalonium.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

For intramammary use.

***** Only for those Member States where space permits *****

The intramammary syringe must only be used once.
The contents of one intramammary syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation. Do not bend the nozzle. Avoid contamination of the nozzle after removing the cap. Before infusion, the teat should be thoroughly cleaned and disinfected (e.g. with the cleaning towel provided).

Option 1: For short nozzle intramammary administration hold the barrel of the intramammary syringe and the base of the cap in one hand and twist off the small upper part of the cap above the indent mark (the base portion of the cap remains on the intramammary syringe) Take care not to contaminate the nozzle.

Option 2: For full nozzle intramammary administration remove the cap fully by holding the barrel of the intramammary syringe firmly on one hand and with the thumb push up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.

Insert the nozzle into the teat canal and apply steady pressure on the intramammary syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter.

After infusion it is advisable to dip the teats in an antiseptic preparation specifically designed for this purpose.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods
Meat and offal: 21 days.
Milk: 96 hours after calving if the dry period is longer than 54 days.
58 days following the treatment if the dry period is less than or equal to 54 days

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins/cephalosporins may occasionally cause severe allergic reactions.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

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

Disposal: read package leaflet.

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

For animal treatment only
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

Univet Ltd,
Tullyvin,
Cootehill,
Co.Cavan
Ireland
H16 T183

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05150/4007

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Polyethylene intramammary syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arentor DC 250mg Intramammary Suspension for dry cows

Cefalonium (as cefalonium dihydrate) 250mg

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefalonium (as cefalonium dihydrate) 250mg

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

4. ROUTE(S) OF ADMINISTRATION

For intramammary use

5. WITHDRAWAL PERIOD(S)

Withdrawal periods
Meat and offal: 21 days.
Milk: 96 hours after calving if the dry period is longer than 54 days.
58 days following the treatment if the dry period is below or equal to 54 days.

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

Read the package leaflet before use.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Arentor DC 250 mg Intramammary Suspension for Dry Cows

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

Marketing authorisation holder and manufacturer responsible for batch release:

Univet Ltd,
Tullyvin,
Cootehill,
Co.Cavan
Ireland
H16 T183

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arentor DC 250mg Intramammary Suspension for Dry Cows

Cefalonium (as cefalonium dihydrate).

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

Each 3g intramammary syringe contains: 250mg cefalonium (as cefalonium dihydrate)
A pale yellow cream-coloured intramammary suspension

4. INDICATION(S)

For the treatment of subclinical mastitis at drying-off and the prevention of new bacterial infections of the udder during the non-lactating period of cows caused by *Staphylococcus aureus, Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Trueperella pyogenes*, *Escherichia coli* and *Klebsiella* spp. susceptible to cefalonium.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to cephalosporins, other ß-lactam antibiotics or to any of the excipients.

Please refer to Section 12 Special warning(s) (Pregnancy and lactation).

6. ADVERSE REACTIONS

In very rare cases immediate hypersensitivity reactions were observed in some animals (restlessness, tremors, swelling of mammary gland, eyelids and lips). These reactions can lead to death.

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

Cattle (Dry cows)

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

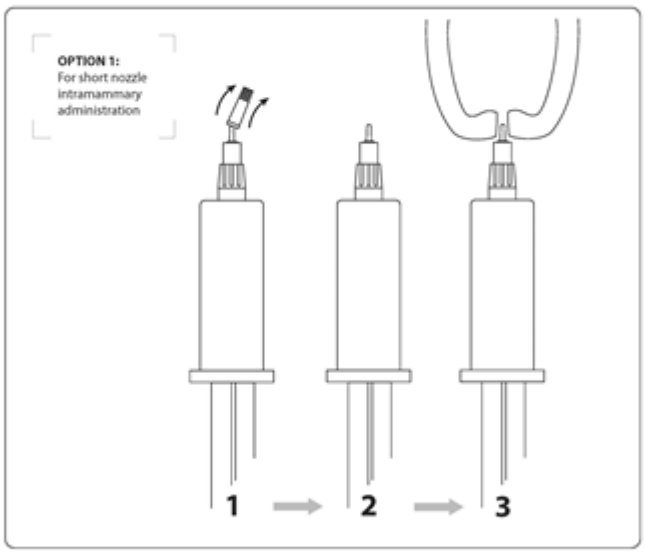
For intramammary use.

The contents of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation.

9. ADVICE ON CORRECT ADMINISTRATION

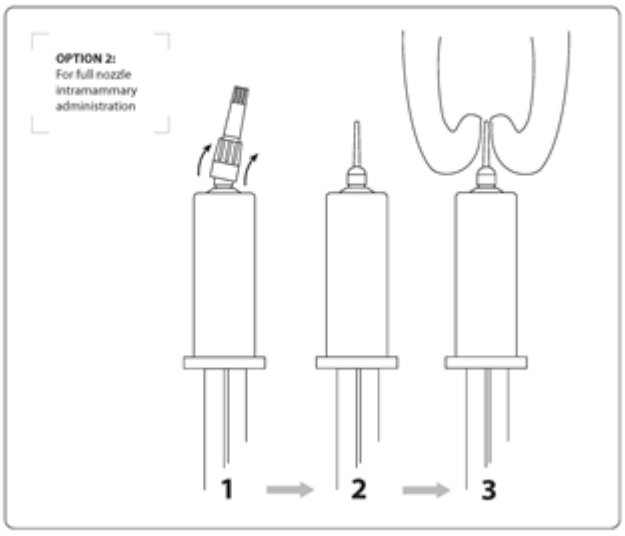
The intramammary syringe must only be used once.
Do not bend the nozzle. Avoid contamination of the nozzle after removing the cap.
Before infusion, the teat should be thoroughly cleaned and disinfected (e.g. with the cleaning towel provided).

Option 1: For short nozzle intramammary administration hold the barrel of the intramammary syringe and the base of the cap in one hand and twist off the small upper part of the cap above the indent mark (the base portion of the cap remains on the intramammary syringe) Take care not to contaminate the nozzle.



Option 2: For full nozzle intramammary administration remove the cap fully by holding the barrel of the intramammary syringe firmly on one hand and with the thumb push

up and along the length of the cap until the cap clicks off. Take care not to contaminate the nozzle.



Insert the nozzle into the teat canal and apply steady pressure on the intramammary syringe plunger until the full dose has been delivered. Holding the end of the teat with one hand, gently massage upwards with the other to aid dispersion of the antibiotic into the quarter.

After infusion it is advisable to dip the teats in an antiseptic preparation specifically designed for this purpose.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 21 days.
Milk: 96 hours after calving if the dry period is longer than 54 days.
58 days following the treatment if the dry period is less than or equal to 54 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after 'EXP'

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Use of the product should be based on susceptibility testing of the bacteria isolated from milk samples 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 package leaflet may increase the prevalence of bacteria resistant to cefalonium and may decrease the effectiveness of treatment with other beta lactams.

Dry cow therapy protocols should take local and national policies on antimicrobial use into consideration, and undergo regular veterinary review.
The feeding to calves of milk containing residues of cefalonium that could select for antimicrobial-resistant bacteria (e.g. production of beta-lactamases) should be avoided up to the end of the milk withdrawal period, except during the colostral phase.

The efficacy of the product is only established against the pathogens mentioned in Section 4 Indications. Consequently, serious acute mastitis (potentially fatal) due to other pathogen species, particularly *Pseudomonas aeruginosa*, can occur after drying off. Good hygienic practices should be thoroughly respected in order to reduce this risk.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Penicillin and cephalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross-sensitivity to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

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, eyes or difficulty breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.
The cleaning towels provided with the intramammary product contain isopropyl alcohol. Wear protective gloves if skin irritation due to isopropyl alcohol is known or suspected. Avoid contact with eyes because isopropyl alcohol can cause eye irritation.

Pregnancy and lactation:
The product is intended for use during the last trimester of pregnancy once the lactating cow has been dried off. There is no adverse treatment effect on the foetus.
The product must not be used in cows that are lactating.

Overdose (symptoms, emergency procedures, antidotes):
Repeated doses in cattle on three consecutive days did not demonstrate or produce any adverse effects.

Major incompatibilities
Not applicable

Interaction with other medicinal products and other forms of interaction:
Cephalosporins should not be administered concurrently with bacteriostatic antimicrobials. Concomitant use of cephalosporins and nephrotoxic drugs may increase renal toxicity.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

XXXXXX

15. OTHER INFORMATION

For animal treatment only

Pack sizes:
Cartons of 20 intramammary syringes and 20 individually wrapped cleaning towels containing isopropyl alcohol.
Buckets of 120 intramammary syringes and 120 individually wrapped cleaning towels containing isopropyl alcohol.

Not all pack sizes may be marketed

Approved: 28 November 2018