PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box/ Plastic Bucket}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Terrexine DC 250mg Intramammary Suspension for Dry Cows

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 3g intramammary syringe contains:

Active substance:

250 mg Cefalonium (as cefalonium dihydrate).

3. PACKAGE SIZE

20 intramammary syringes
120 intramammary syringes

4. TARGET SPECIES

Cattle (dry cows).

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

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.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the Package Leaflet before Use

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For Animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.
{Univet company logo}

14. MARKETING AUTHORISATION NUMBERS

Vm 05150/5002

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

User warnings
Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Polyethylene intramammary syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Terrexine DC

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cefalonium (cefalonium dihydrate) 250mg/3g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Terrexine DC 250mg Intramammary Suspension for Dry Cows

2. COMPOSITION

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

3. TARGET SPECIES

Cattle (dry cows).

4. INDICATIONS FOR USE

For the treatment of subclinical mastitis at drying-off 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 6 Special warnings (Pregnancy and lactation).

6. SPECIAL WARNINGS

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.

Use of the veterinary medicinal 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 of waste milk containing residues of cefalonium to calves should be avoided up to the end of the milk withdrawal period (except during the colostral phase), because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

The efficacy of the veterinary medicinal 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 veterinary medicinal product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this veterinary medicinal 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 package leaflet or the label to the physician. 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 veterinary medicinal 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:
The veterinary medicinal 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.

Lactation:
The veterinary medicinal product must not be used in cows that are lactating.

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.

Overdose:
Repeated doses in cattle on three consecutive days did not demonstrate or produce any adverse effects.

Major incompatibilities:
Not applicable.

7. ADVERSE EVENTS

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions (restlessness, tremor, swelling of mammary gland, eyelids and lips)[1]

[1] Immediate reactions observed in some animals which can lead to death.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

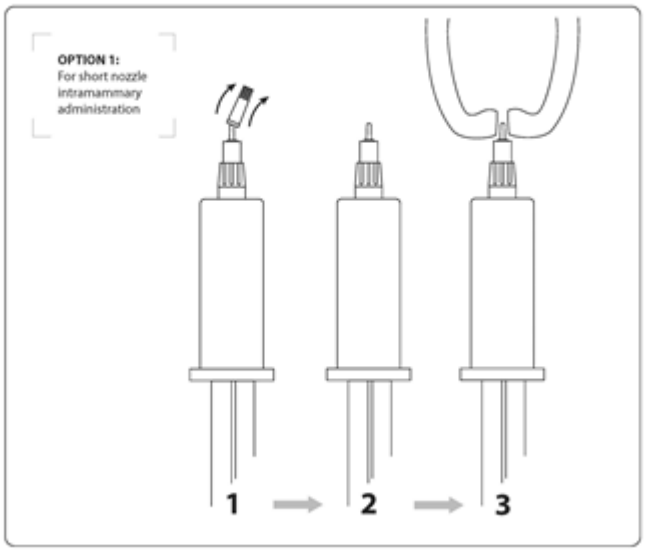
For intramammary use.

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

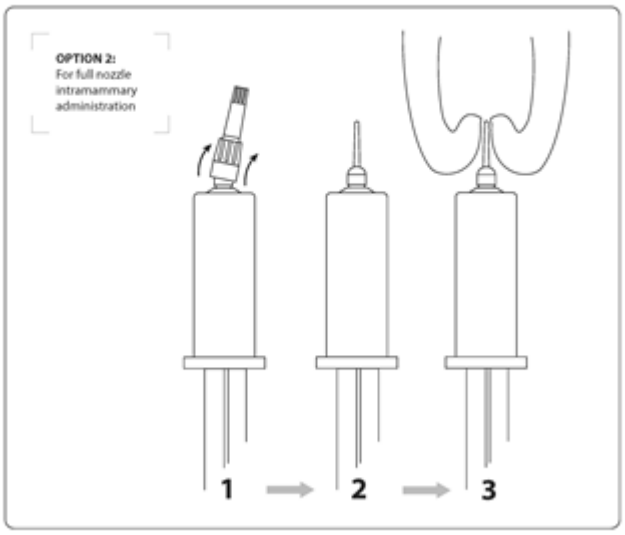
9. ADVICE ON CORRECT ADMINISTRATION

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 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.

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

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 05150/5002

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland

Local representatives and contact details to report suspected adverse reactions:

DUGV Uk Ltd
Union House
111 New Union Street
Coventry, England, CV1 2NT
Tel: +353 (0) 504 43169
e-mail: pv@dugganvet.ie

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION

Gavin Hall

Approved 26 January 2025