1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arentor DC 250mg Intramammary Suspension for Dry Cows

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3g intramammary syringe contains:

Active substance:
Cefalonium 250 mg (as cefalonium dihydrate)

Excipients:

Qualitative composition of excipients and other constituents
Aluminium distearate
Liquid Paraffin

A pale yellow cream-coloured suspension

3. CLINICAL INFORMATION

3.1 Target species

Cattle (dry cows).

3.2 Indications for use for each target species

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.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 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 pathogens. 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 SPC 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 3.2 Indications for use for each target species. 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 or 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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.

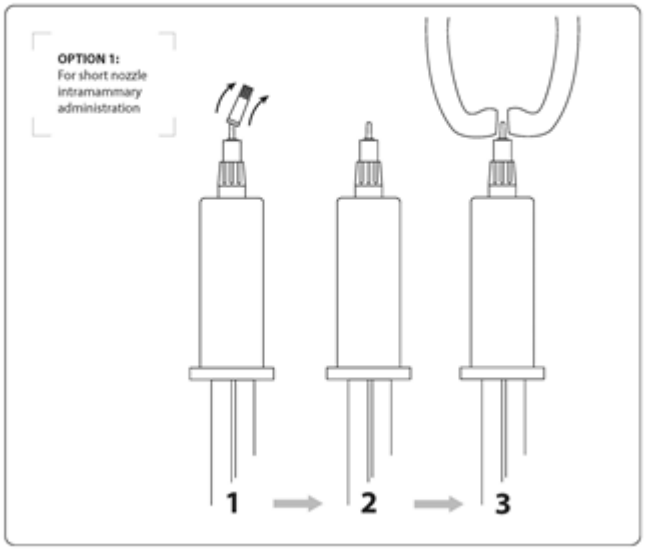
3.8 Interaction with other medicinal products and other forms of interaction

Cephalosporins should not be administered concurrently with bacteriostatic antimicrobials. Concomitant use of cephalosporins and nephrotoxic drugs may increase renal toxicity.

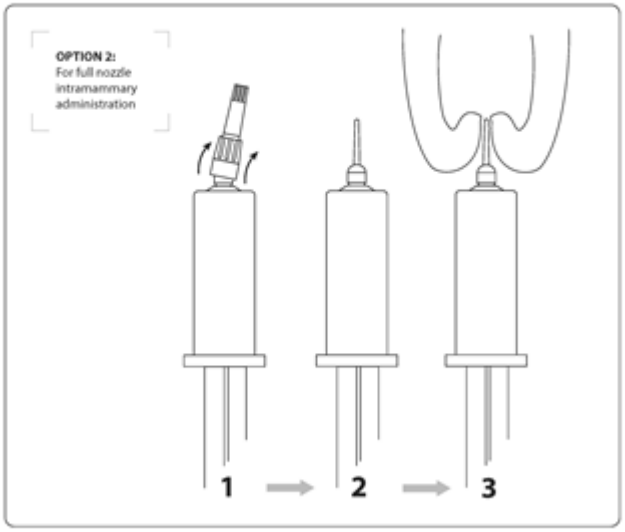
3.9 Administration routes and dosage

For intramammary use.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 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.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QJ51DB90

4.2 Pharmacodynamics

Cefalonium is an antibacterial drug of the first generation cephalosporin group which acts by inhibition of cell wall synthesis (bactericidal mode of action). The antibacterial activity is not impaired in the presence of milk.

Three mechanisms of resistance to cephalosporin are known: reduced permeability of the cell wall, enzymatic inactivation and absence of specific penicillin binding sites. In Gram-positive bacteria and particularly staphylococci, the main cephalosporin resistance mechanism is through alteration of penicillin binding proteins. In Gram-negative bacteria resistance may consist in the production of (broad- or extended-spectrum) β-lactamases.

Cefalonium is active against *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Trueperella pyogenes*, *Escherichia coli* and *Klebsiella* spp. susceptible to cefalonium.

4.3 Pharmacokinetics

Cefalonium is extensively but slowly absorbed from the udder and excreted primarily in the urine. Between 7 and 13% of the active substance is eliminated in urine on each of the first three days post dosing whilst daily excretion in faeces is < 1% over the same period.

Mean blood concentration remains fairly constant during approximately 10 days after dosing which is consistent with slow but prolonged absorption of cefalonium from the udder.

The long term persistence of cefalonium in the dry udder was examined over a time span of 10 weeks after infusion. Effective levels of cefalonium in udder secreta remain up to 10 weeks after infusion.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

A 3g coloured low density polyethylene intramammary syringe with a coloured low density polyethylene dual cap.

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.

5.5 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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/050/001

8. DATE OF FIRST AUTHORISATION

07/12/2018

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

07/03/2024

10. 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).