SUMMARY OF PRODUCT CHARACTERISTICS

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:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension
A pale yellow cream-coloured suspension

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (dry cows)

4.2 Indications for use, specifying the target species

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.

4.3 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 4.7

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 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 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 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 4.2 Indications for use. 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 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 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.

4.6 Adverse reactions (frequency and seriousness)

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, including isolated reports treated).

4.7 Use during pregnancy, lactation or lay

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.

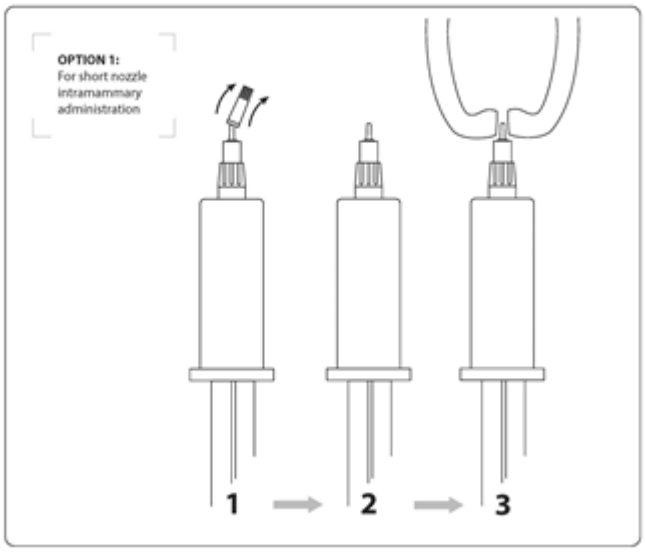
4.8 Interaction with other medicinal products and other forms of interaction

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

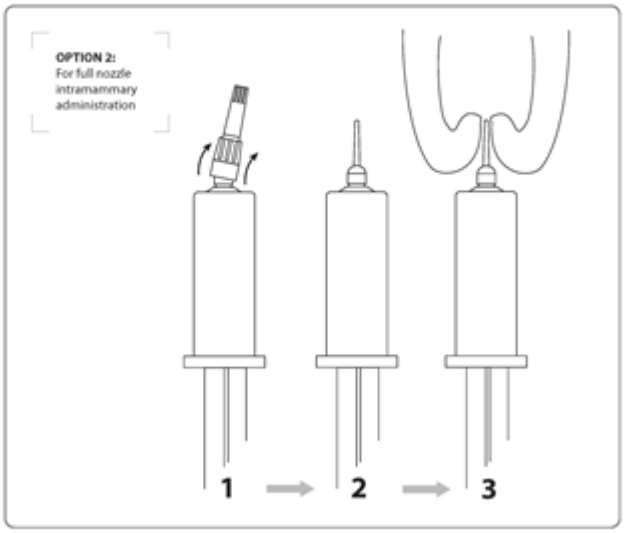
4.9 Amounts to be administered and administration route

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.

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

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

4.11 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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other beta-lactam antibacterials for intramammary use, first-generation cephalosporins.
ATC vet code: QJ51DB90.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium distearate
Liquid Paraffin

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

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

6.4 Special precautions for storage

Do not store above 25°C.

6.5 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.
Buckets of 120 intramammary syringes and 120 individually wrapped cleaning towels containing isopropyl alcohol.

Not all pack sizes may be marketed

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Univet Ltd
Tullyvin
Cootehill
Co. Cavan
Ireland
H16 T183

8. MARKETING AUTHORISATION NUMBER

Vm 05150/4007

9. DATE OF FIRST AUTHORISATION

28 November 2018

10. DATE OF REVISION OF THE TEXT

November 2018

Approved: 28 November 2018