1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Seclaris DC 250 mg Intramammary Suspension for dry cows

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each intramammary syringe of 3 g contains:

Active substance:
Cefalonium (as cefalonium dihydrate) 250 mg

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary suspension
Shiny off-white to yellowish ointment.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (dry cow).

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 cefalosporins, other ß-lactam antibiotics or to any of the excipients.

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 bacteria isolated from milk samples obtained from the udder quarter(s) of each cow to be dried off. If this is not possible, therapy should be based on local (regional, farm level) risk based epidemiological information about the expected pathogen challenge, and susceptibility of target bacteria. Use of the product deviating from the instructions given in the SPC may contribute to the development of bacterial resistance to cefalonium which may also 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. ESBL) 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

Wash hands after use.
Penicillin and cefalosporins may cause sensitisation (allergy) following injection, inhalation, ingestion or skin contact. Sensitivity to penicillin may lead to cross-sensitivity to cefalosporin 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.
The cleaning towels supplied with this product contain isopropyl alcohol, which may cause skin or eye irritation in some people. It is recommended to wear protective gloves when administering the product and handling the cleaning towels.

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 may lead to death.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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.
Do not use in cows that are lactating.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

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. After milking is complete, thoroughly clean and disinfect the end of the teat with the cleaning towel provided. There are two options for administration of the product:

Option 1: For short nozzle intramammary administration
Hold the barrel of the 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 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 syringe firmly in 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 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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: other beta-lactam antibacterials for intramammary use, first-generation cefalosporins.
ATCvet Code: QJ51DB90

5.1 Pharmacodynamic properties

Cefalonium is an antibacterial drug of the first generation cefalosporin group which acts by inhibition of cell wall synthesis (bactericidal mode of action).

Three mechanisms of resistance to cefalosporin 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 cefalosporin 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 remained up to 10 weeks after infusion.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate.
Liquid paraffin.

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

White polyethylene syringes with red polyethylene caps.
Cleaning towels (70% viscose / 30% polyester, alcohol impregnated) in paper aluminium copolymer laminate sachets.

Pack sizes:
20 intramammary syringes and 20 cleaning towels
72 intramammary syringes and 72 cleaning towels

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Ceva Santé Animale
10, avenue de La Ballastière
33500 Libourne
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10815/047/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th December 2017

10 DATE OF REVISION OF THE TEXT