SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK: Kepravine Dry Cow 250 mg Intramammary suspension

AT, CY, DE, EE, LT, LV, MT, NL: Cepravin Dry Cow 250 mg Intramammary suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each intramammary syringe with 3 g suspension contains:

Active substance:
250 mg Cefalonium (as cefalonium dihydrate)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension.
White to cream coloured suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dairy cattle (cows at drying off).

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 caused by *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus uberis*, *Trueperella pyogenes*, *Escherichia coli* and *Klebsiella spp.* during the non-lactating period of cows.

4.3 Contraindications

Do not use in animals known to be hypersensitive to cephalosporin antibiotics and other β-lactam antibiotics.
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 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 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 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 package leaflet or the label to the physician. Swelling of the face, lips or eyes or breathing difficulties are more serious symptoms and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None known.

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.
Not to be used in lactating cows.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For intramammary use.

The content of one syringe should be infused into the teat canal of each quarter immediately after the last milking of the lactation. Before infusion, the teat should be thoroughly cleaned and disinfected with the cleaning towel provided.
Avoid contamination of the nozzle after removing the cap. Do not bend the nozzle.

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 short exposed part of 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.
Finally immerse the teats in a teat dip.

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:

- Interval treatment-calving ≥ 54 days: withdrawal period = 96 hours after calving.
- Interval treatment-calving < 54 days: withdrawal period = 54 days plus 96 hours after treatment, ensuring that at least 7 complete milkings are discarded.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: First-generation cephalosporins; cefalonium
ATCvet 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).
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..

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 distearate
Liquid paraffin

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4. Special precautions for storage

Do not store above 30 °C.
Do not freeze.

6.5 Nature and composition of immediate packaging

Single dose 3g white polyethylene syringes with a red polyethylene dual push-fit cap.
Boxes of 20 intramammary syringes with cleaning towels.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet UK Ltd

Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4587

9. DATE OF FIRST AUTHORISATION

24 September 2012

10. DATE OF REVISION OF THE TEXT

September 2017

Approved: 13 September 2017