PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kepravine Dry Cow 250 mg Intramammary suspension (Name in United Kingdom, Reference Member State)

Cepravin Dry Cow 250 mg Intramammary suspension (Name in Concerned Member States)
Cefalonium

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

250 mg Cefalonium (as cefalonium dihydrate)/syringe

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

Box of 20 intramammary syringes with cleaning towels.

5. TARGET SPECIES

Dairy cattle (cows at drying off)

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet for use.
For intramammary use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNINGS, IF NECESSARY

10. EXPIRY DATE

<EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4587

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kepravine Dry Cow 250 mg Intramammary suspension (Name in United Kingdom, Reference Member State)

Cepravin Dry Cow 250 mg Intramammary suspension (Name in Concerned Member States)
Cefalonium

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

250 mg Cefalonium (as cefalonium dihydrate)/syringe

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

Meat and offal: 21 d
Milk: Read the package leaflet before use

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

<EXP {month/year}>

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Ad us vet.

PACKAGE LEAFLET:
Kepravine Dry Cow 250 mg Intramammary suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

<Marketing authorisation holder <and manufacturer>>:

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

<Manufacturer for the batch release:>

Schering-Plough Animal Health
La Grindoliere,
Zone Artisanale,
49500 Segre
France

Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

2. 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
Cefalonium

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

250 mg Cefalonium (as cefalonium dihydrate)
White to cream coloured intramammary suspension

4. INDICATIONS

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.

5. CONTRAINDICATIONS

Do not use in animals known to be hypersensitive to cephalosporin antibiotics and other β-lactam antibiotics.
Not to be used in lactating cows.

6. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dairy cattle (cows at drying off).

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30 °C.
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

Pregnancy and Lactation:
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 intended for use within 54 days of calving.
Not to be used in lactating cows.
Overdose (symptoms, emergency procedures, antidotes):

Repeated doses in cattle on three consecutive days did not demonstrate or produce any adverse effects.
To be supplied only on veterinary prescription.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package size: 20 intramammary syringes with 3 g suspension and cleaning towels.

Approved: 13 September 2017