ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON
(identical wordings for packages of 3, 15, 20 and 24 syringes)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LC, 75mg, intramammary ointment for lactating cattle
Cefquinome (as sulphate)

2. STATEMENT OF ACTIVE SUBSTANCES

Cefquinome (as sulphate) 75 mg

3. PHARMACEUTICAL FORM

Intramammary ointment

4. PACKAGE SIZE

3 syringes and 3 cleaning towels
15 syringes and 15 cleaning towels
20 syringes and 20 cleaning towels
24 syringes and 24 cleaning towels

5. TARGET SPECIES

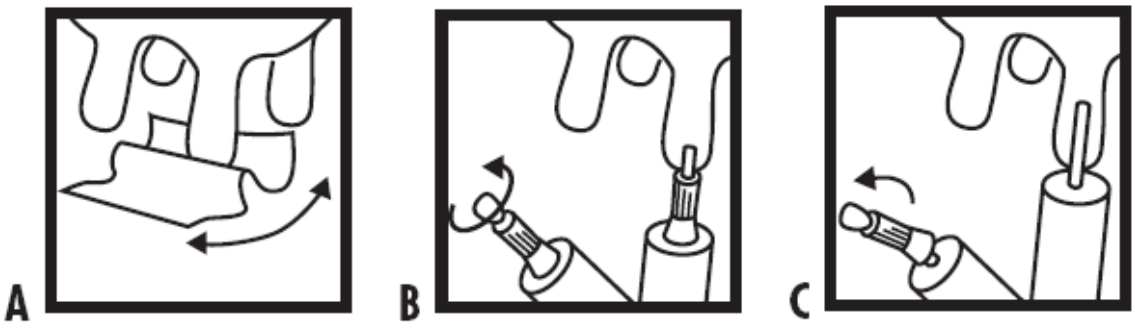
Lactating cows

6. INDICATION(S)

For the treatment of clinical mastitis in lactating cows.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.



A) Clean teat with enclosed cleaning towel
B) For partial insertion, break top of cap as shown
C) For full insertion, remove whole cap

Do not touch the cannula with your fingers.
Infuse the ointment carefully.Partly used syringes should be discarded.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 4 days
Milk: 5 days (120 hours)

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package insert for advice on correct administration.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

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

Disposal: read package leaflet.

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 01708/4451

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LC, 75mg, intramammary ointment for lactating cattle
Cefquinome (as sulphate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Cefquinome (as sulphate) 75 mg

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

Each syringe with 8 g ointment contains: Cefquinome 75 mg

4. ROUTE(S) OF ADMINISTRATION

Intramammary

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal: 4 days
Milk: 5 days (120 hours)

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Cobactan LC, 75mg, intramammary ointment for lactating cattle

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

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LC, 75mg, intramammary ointment for lactating cattle
Cefquinome (as sulphate)

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

Cefquinome 75 mg
White to slightly yellow, oily viscous homogeneous intramammary ointment.

4. INDICATION(S)

For the treatment of clinical mastitis in lactating cows caused by *Staphylococcus aureus, Streptococcus uberis, Streptococcus dysgalactiae, Escherichia coli* and other enterobacteria susceptible to cefquinome.

5. CONTRAINDICATIONS

Not to be administered to animals which are known to be hypersensitive to cefquinome or to penicillins.
Do not use the cleaning towel if lesions are present on the teat.

6. ADVERSE REACTIONS

In very rare cases anaphylactic reactions have been noted in animals after administration of the product.

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 treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Lactating cows.

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

Gently infuse the contents of one syringe into the teat canal of the infected quarter every 12 hours after each of 3 successive milkings.

9. ADVICE ON CORRECT ADMINISTRATION

Milk out the affected quarter(s). After thoroughly cleaning and disinfecting the teat and teat orifice, gently infuse the contents of one syringe into each affected quarter. Disperse the product by gently massaging the teat and udder of the affected animal.

The syringe must only be used once. Partly used syringes should be discarded.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment. Cows may not be slaughtered for human consumption until 4 days after the last treatment.

Milk must not be taken for human consumption during treatment. Milk must be discarded until 5 days (120 hours) after the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C

Do not use this veterinary medicinal product after the expiry date which is stated on the 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 and take into account official and local antimicrobial policies. Inappropriate use of the product may increase the prevalence of bacteria resistant to cefquinome and may decrease the effectiveness of treatment with cephalosporins, due to the potential for cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity to cephalosporin and vice versa. Allergic reactions to these substances may occasionally be serious.

1. Handle this product with great care to avoid exposure, taking all recommended precautions.

2. Do not handle this product if you know you are sensitive to such preparations, or if you have been advised not to work with them.

3. If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the Doctor this warning. Swelling of the face, lips and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Wash hands after using the cleaning towels and wear protective gloves if skin irritation due to Isopropyl alcohol is known or suspected.

Pregnancy and lactation:

The product is intended for use during lactation. There is no available information indicating reproductive toxicity (inc. teratogenicity) in cattle. In reproductive toxicity studies in laboratory animals cefquinome did not reveal any effect on reproduction or teratogenic potential.

Interaction with other medicinal products and other forms of interaction:

It is known that a cross sensitivity to cephalosporins exists for bacteria sensitive to the cephalosporin group.

Overdose (symptoms, emergency procedures, antidotes):

No symptoms expected or emergency procedures required.

Incompatibilities:

None known.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist 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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Package quantities:
Packs of 3, 15, 20 and 24 syringes.
Cleaning towels are included in the carton.
Not all pack sizes may be marketed.

Approved 02 July 2019