PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan MC Intramammary Suspension 75 mg Milking Cow
Cefquinome (as sulphate)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each syringe contains 75 mg cefquinome

3. PHARMACEUTICAL FORM

Intramammary Suspension

4. PACKAGE SIZE

15 syringes
30 syringes

5. TARGET SPECIES

Lactating cows

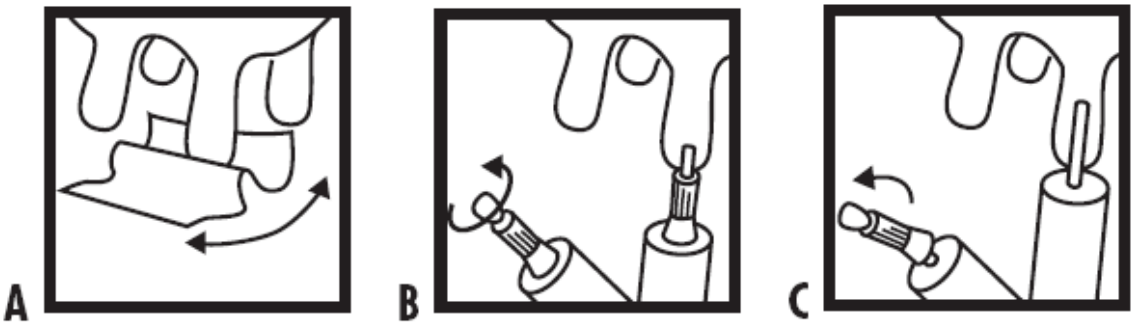
6. INDICATION(S)

For the treatment of clinical mastitis in lactating dairy 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)

Meat and offal 4 days
Milk: 5 days (120 hours)
For withdrawal periods when used in combination with Cobactan 25 mg/ml, see package leaflet.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep container in outer carton.

12. SPECIFIC 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

[Distribution category]

For animal treatment only.
POM-V
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

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4444

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE
Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan MC Intramammary Suspension 75 mg Milking Cow
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

Contains 75 mg cefquinome per 8 g syringe

4. ROUTE(S) OF ADMINISTRATION

Intramammary.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods: Meat and offal 4 days, Milk: 5 days (120 hours).

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

Exp. End of:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-V
To be supplied only on veterinary prescription.

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

Keep out of sight and reach of children.

10. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4444

PACKAGE LEAFLET FOR:

Cobactan MC Intramammary Suspension 75 mg Milking Cow

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

Marketing Authorisation Holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturers responsible for batch release:
Intervet International GmbH
Feldstrasse 1a
85716 Unterschleissheim
Germany

and

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan MC Intramammary Suspension 75 mg Milking Cow
Cefquinome (as sulphate)

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

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 cephalosporin antibiotics and other beta-lactam antibiotics
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 the medicine has not worked, please inform your veterinary surgeon. Alternatively, you can report via your national reporting system.

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 with the cleaning towel provided, 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)

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

When using Cobactan MC and Cobactan 25 mg/ml in combination, the withdrawal periods are as follows: Meat and offal 5 days, Milk 5 days (120 hours).

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25º C.
Keep out of the sight and reach of children.

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. 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

November 2023

15. OTHER INFORMATION

Legal category
POM-V To be supplied only on veterinary prescription.
Package Quantities
Packs of 3, 15, 20, 24 and 30 syringes.
Cleaning towels are included in the carton.
Not all pack sizes may be marketed.

Further information
With other milking routines, the basis of the veterinary surgeons advice should be that milk may be taken for human consumption only after the same period from the last treatment. For example, with three times a day milking, milk may be taken for human consumption only at the 12th milking.
In vitro, Cefquinome has antibiotic activity against common Gram negative and Gram positive bacteria including *Escherichia coli, Staphylococcus aureus, Streptococcus dysgalactiae, Streptococcus agalactiae and Streptococcus uberis.*

Combined Therapy
Cobactan 25 mg/ml and Cobactan MC can be used concurrently.
For the treatment of *E.coli* mastitis, experimental challenge studies have shown that the use of Cobactan 25 mg/ml in combination with Cobactan MC lead to an improvement in efficacy, particularly in terms of bacterial cure rate.

For combined therapy the following treatment regime should be followed:

Cobactan 25 mg/ml	Cobactan MC
1 mg cefquinome/kg bodyweight (bw) (2 ml/50 kg bw) ↓ 24 hours ↓ 1 mg cefquinome/kg bodyweight (bw) (2 ml/50 kg bw)	One syringe gently infused into the teat of the infected quarter ↓ 12 hours ↓ One syringe gently infused into the teat of the infected quarter ↓ 12 hours ↓ One syringe gently infused into the teat of the infected quarter

Marketing Authorisation Number
Vm 01708/4444

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24
Ireland

Approved: 14 February 2024