PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan 25 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Cefquinome (as sulfate) 25 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Target species: Cattle and pigs

6. INDICATION(S)

Not applicable for the outer package.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular administration

8. WITHDRAWAL PERIOD

Cattle:
meat and offal – 5 days
milk – 24 hours.
In combination with Cobactan MC: meat and offal – 5 days; milk – 120 hours.

Pigs:
meat and offal: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

10. EXPIRY DATE

EXP
Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.
Shake well before use.
Keep the container in the outer carton.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulatory authority.

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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4445

17. MANUFACTURER'S BATCH NUMBER

BN

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan 25 mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 25 mg Cefquinome per ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Target species: Cattle and pigs

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intramuscular administration

8. WITHDRAWAL PERIOD

Cattle:
meat and offal – 5 days
milk – 24 hours.
In combination with Cobactan MC: meat and offal – 5 days; milk – 120 hours.

Pigs:
meat and offal: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

For uses, dosage, contra-indications, disposal advice, and warnings: see package leaflet.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.
Shake well before use.
Keep the container in the outer carton.

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

For uses, dosage, contra-indications, disposal advice, and warnings: see 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 reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4445

17. MANUFACTURER'S BATCH NUMBER

BN

PACKAGE LEAFLET FOR:

Cobactan 25 mg/ml suspension for injection

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

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstraße 1A
85716 Unterschleißheim
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan 25 mg/ml suspension for injection

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

Active substance: Cefquinome (as sulphate) 25 mg/ml

4. INDICATION(S)

For the treatment of bacterial infections in cattle and pigs caused by the Gram positive and Gram negative microorganisms sensitive to cefquinome.
Cattle:
Respiratory disease caused by Pasteurella multocida and Mannheimia haemolytica
Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)
Acute *E.coli* mastitis with signs of systemic involvement.

Calves:
E.coli septicaemia in calves

Pigs:
For the treatment of bacterial infections of the lungs and respiratory tract caused by *Pasteurella multocida, Haemophilus parasuis, Actinobacillus pleuropneumoniae, Streptococcus suis* and other cefquinome-sensitive organisms
Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *E.coli, Staphylococcus spp., Streptococcus spp*. and other cefquinome sensitive organisms.

Piglets:
Reduction of mortality in cases of meningitis caused by *Streptococcus suis*.
For the treatment of:
Arthritis caused by *Streptococcus ssp., E. coli* and other cefquinome-sensitive organisms.
Epidermitis (mild or moderate lesions) caused by *Staphylococcus hyicus.*

5. CONTRAINDICATIONS

Do not use Cobactan 25 mg/ml in animals, which are known to be hypersensitive to ß-lactam antibiotics.
Do not administer to animals less than 1.25 kg body weight.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. ADVERSE REACTIONS

Use of the veterinary medicinal product may result in localized tissue reaction.
Tissue lesions are repaired 15 days after the last administration of the veterinary medicinal product.
Hypersensitivity reactions to cephalosporins occur rarely.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and pigs

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

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by *Pasteurella multocida* and M. haemolytica Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
	Acute *E. coli* mastitis with signs of systemic involvement	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 2 consecutive days
Calves	*E. coli* septicaemia	2 mg cefquinome/kg bw (4 ml/50 kg bw)	Once daily for 3 or 5 consecutive days

Pigs	Respiratory disease	2 mg Cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 3 consecutive days.
	MMA	2 mg Cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 2 consecutive days.
Piglets	Meningitis Arthritis Epidermitis	2 mg Cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 5 consecutive days

All treatments to be given by intramuscular injection. Studies have indicated the advisability of giving second and subsequent injections at a different injection site. The preferred injection site is in muscular tissue in the mid neck.
Shake the vial well before using.

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
1mg cefquinome/kg bw (2ml/50 kg bw) ↓ 24 hours ↓ 1mg cefquinome/kg bw (2ml/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

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
The veterinary medicinal product does not contain an antimicrobial preservative.
Swab the septum before removing each dose. Use a dry sterile needle and syringe.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small

volumes, for example when treating piglets. The cap may be safely punctured up to 25 times. The 50ml vial should be used for treating small piglets. When treating groups of animals, use a draw-off needle.

10. WITHDRAWAL PERIOD(S)

Cattle:
meat and offal – 5 days
milk – 24 hours.
When using Cobactan 25 mg/ml and Cobactan MC Intramammary suspension in combination for the treatment of acute E. coli mastitis in cattle, the withdrawal periods are as follows; meat and offal - 5 days, milk - 5 days (120 hours).**Pigs:**
meat and offal: 3 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children. Do not store above 25°C. Protect from light.
Do not use after the expiry date stated on the label. Shelf-life after first opening of the container: 28 days
When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet,
the date on which any product remaining in the container should be discarded should be worked out. This discard
date should be written in the space provided on the label. (Please ensure an appropriate space is provided on the
label or carton for the user to record the discard date)

12. SPECIAL WARNING(S)

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

1. Do not handle this veterinary medicinal product if you know you are sensitized, or if you have been advised not to work with such preparation.

2. Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.

3. 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 with breathing, are more serious symptoms and
require urgent medical attention.

Wash hands after use.

Use of Cobactan 25 mg/ml may constitute a risk to public health due to spread of antimicrobial resistance.
Cobactan 25 mg/ml should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given, may increase the prevalence of resistance. Whenever possible, Cobactan 25 mg/ml should only be used based on susceptibility testing.

Cobactan 25 mg/ml is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

There is no available information indicating reproductive toxicity in cattle or pigs. In reproduction toxicity studies in laboratory animals cefquinome did not reveal any effect on reproduction or teratogenic potential.

Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

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

Due to undesirable pharmacodynamic interaction, do not apply cefquinome simultaneously with pharmaceuticals acting bacteriostatically.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulatory authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

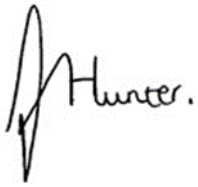
March 2021

15. OTHER INFORMATION

Pack sizes: This product is supplied in cartons containing either one 50 ml vial or one 100 ml vial
Not all pack sizes may be marketed.

POM-V To be supplied only on veterinary prescription

Vm 01708/4445

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

Approved 12 March 2021