PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(carton box for the 50-ml vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension for injection for cattle and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Carton box containing one 50 ml vial

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

Not applicable for the outer package.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use. Intramuscular administration.

8. WITHDRAWAL PERIOD

Species	Product	Withdrawal Period
Cattle	Meat and offal	5 days
Cattle	Milk	24 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 insert for user warnings.

10. EXPIRY DATE

<EXP {month/year}>
Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

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

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

Any unused product or waste material should be disposed of in accordance with national 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
Represented in <country> by <national Intervet company>

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(carton box for the 100-ml vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension for injection for cattle and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Carton box containing one 100 ml vial

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

Not applicable for the outer package.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use. Intramuscular administration.

8. WITHDRAWAL PERIOD

Species	Product	Withdrawal Period
Cattle	Meat and offal	5 days
Cattle	Milk	24 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 insert for user warnings.

10. EXPIRY DATE

<EXP {month/year}>
Shelf-life after first opening the container: 28 days

11. SPECIAL STORAGE CONDITIONS

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

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

Any unused product or waste material should be disposed of in accordance with national 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
Represented in <country> by <national Intervet company>

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(label for the 50-ml vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension for injection for cattle and pigs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATIONS

Not applicable for the immediate packaging.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use. Intramuscular administration.

8. WITHDRAWAL PERIOD

Species	Product	Withdrawal Period
Cattle	Meat and offal	5 days
Cattle	Milk	24 hours
Pigs	Meat and offal	3 days

9. SPECIAL WARNING(S), IF NECESSARY

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

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
<Once broached,/opened, use by…>

11. SPECIAL STORAGE CONDITIONS

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

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

Any unused product or waste material should be disposed of in accordance with national 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
Represented in <country> by <national Intervet company>

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(label for the 100-ml vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension for injection for cattle and pigs

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

Cattle and pigs

6. INDICATIONS

Not applicable for the immediate packaging.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use. Intramuscular administration.

8. WITHDRAWAL PERIOD

Species	Product	Withdrawal Period
Cattle	Meat and offal	5 days
Cattle	Milk	24 hours
Pigs	Meat and offal	3 days

9. SPECIAL WARNING(S), IF NECESSARY

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

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month/year}>
<Once broached,/opened, use by…>

11. SPECIAL STORAGE CONDITIONS

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

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

Any unused product or waste material should be disposed of in accordance with national 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands
Represented in <country> by <national Intervet company>

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

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

PACKAGE LEAFLET

COBACTAN 2.5% w/v suspension for injection for cattle and pigs

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

Name and address of the Marketing Authorisation Holder:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
THE NETHERLANDS

Name and address of the Marketing Authorisation Holder responsible for batch release

Intervet International GmbH
Feldstraße 1A
85716 Unterschleißheim
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

COBACTAN 2.5% w/v suspension for injection for cattle and pigs

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

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

4. INDICATIONS

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 2.5% 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, ROUTES AND METHOD OF ADMINISTRATION

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by *Pasteurella*	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 or 5

	multocida and M. haemolytica Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)		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.

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

Species	Product	Withdrawal Period
Cattle	Meat and offal	5 days
Cattle	Milk	24 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 WARNINGS

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.
4. 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.

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.

Use of Cobactan 2.5% may constitute a risk to public health due to spread of antimicrobial resistance.
Cobactan 2.5% 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 2.5% should only be used based on susceptibility testing.

Cobactan 2.5% 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.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.