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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LA 7.5% w/v suspension for injection for swine
Cefquinome

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance : Cefquinome (as sulfate) 75 mg
Excipients
Aluminium stearate , Triglycerides medium-chain

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Carton box with 50 ml vial

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use. Intramuscular administration.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs (meat and offal)*:* 7 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 {month/year}
Shelf-life after first opening the container: 28 days
Once broached/opened, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product 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 International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Represented in the UK by:
Intervet UK Ltd
Walton Manor
Walton

Milton Keynes
Buckinghamshire
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4573

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 LA 7.5% w/v suspension for injection for swine
Cefquinome

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substance:Cefquinome (as sulfate) 75 mg
Excipients
Aluminium stearate , Triglycerides medium-chain

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Carton box with 100 ml vial

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use. Intramuscular administration.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs (meat and offal)*:* 7 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 {month/year}
Shelf-life after first opening the container: 28 days
Once broached/opened, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product 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 International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Represented in the UK by:
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4573

17. MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(Carton box for the 250 ml vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LA 7.5% w/v suspension for injection for swine
Cefquinome

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Active substanceCefquinome (as sulfate) 75 mg
Excipients
Aluminium stearate , Triglycerides medium-chain

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Carton box with 250 ml vial

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use. Intramuscular administration.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs (meat and offal)*:* 7 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 {month/year}
Shelf-life after first opening the container: 28 days
Once broached/opened, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product 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 International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Represented in the UK by:
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4573

17. MANUFACTURER'S BATCH NUMBER

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

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
(label for the 50-ml vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LA 7.5% w/v suspension for injection for swine
Cefquinome

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains:
Active substance : Cefquinome (as sulfate) 75 mg

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular administration.

5. WITHDRAWAL PERIOD

Withdrawal period
Pigs (meat and offal)*:* 7 days

6. Batch number

<Batch> <Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once broached/opened, use by:

8. 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.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
(label for the 100-ml vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LA 7.5% w/v suspension for injection for swine
Cefquinome

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains:
Active substance : Cefquinome (as sulfate) 75 mg

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

100 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular administration.

5. WITHDRAWAL PERIOD

Withdrawal period
Pigs (meat and offal)*:* 7 days

6. Batch number

<Batch> <Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once broached/opened, use by:

8. 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.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
(label for the 250-ml vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LA 7.5% w/v suspension for injection for swine
Cefquinome

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains:
Active substance :Cefquinome (as sulfate) 75 mg

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

250 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular administration.

5. WITHDRAWAL PERIOD

Withdrawal period
Pigs (meat and offal)*:* 7 days

6. Batch number

<Batch> <Lot> {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once broached/opened, use by:

8. 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.

PACKAGE LEAFLET

Cobactan LA 7.5% w/v suspension for injection for swine

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

Represented in the UK by:
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer for the batch release:
Intervet International GmbH
Feldstrasse 1A
85716 Unterschleissheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan LA 7.5% w/v suspension for injection for swine
Cefquinome

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

Each ml contains:
Active substance : Cefquinome (as sulfate) 75 mg
Excipients
Aluminium stearate , Triglycerides medium-chain
Suspension for injection. White to off-white resuspendable suspension

4. INDICATION(S)

For the treatment of swine respiratory disease (SRD) associated with *Pasteurella multocida*, *Actinobacillus pleuropneumoniae and Haemphilus parasuis* sensitive to cefquinome.

5. CONTRAINDICATIONS

Not to be administered to animals which are known to be hypersensitive to cephalosporin antibiotics and other β-lactam antibiotics.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. ADVERSE REACTIONS

Pain at injection was very commonly observed in a clinical study. Limited macroscopic lesions (2x5cm area) were observed after intramuscular injection at the injection site of treated animals in a clinical study. The lesions were reversible. For single animals this took up to 14 days after treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

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

For intramuscular administration: two injections with 48 hours interval.
3.0 mg cefquinome/kg bodyweight (equivalent to 1 ml of Cobactan LA 7.5% w/v /25 kg bodyweight).

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial well before using.
To ensure the correct dosage and to avoid possible underdosing, body weight should be determined as accurately as possible.
It is recommended to divide the dose so that no more than 3 ml of the product are injected at one site. Do not use the same injection site more than once during a course of treatment.
The rubber stopper of the vial may be safely punctured up to 20 times. Otherwise, the use of a multiple-dose syringe is recommended.

10. WITHDRAWAL PERIOD

Pigs (meat and offal)*:* 7 days

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 and vial after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 28 days

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

"Use of Cobactan LA 7.5% w/v suspension for injection for swine may constitute a risk to public health due to spread of antimicrobial resistance.
Cobactan LA 7.5% w/v suspension for injection for swine 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 LA 7.5% w/v suspension for injection for swine should only be used based on susceptibility testing. "

Cobactan LA 7.5% w/v suspension for injection for swine 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.

In food borne pathogens, co-resistance can occur for various antimicrobial substances including aminoglycosides, sulphonamides and trimethoprim compounds, chloramphenicol, ciprofloxacin, gentamycin and tetracycline.

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 product if you know you are sensitized to penicillins and cephalosporins, or if you have been advised not to work with such preparation.

2. Handle this product with great care to avoid exposure by accidental contact with the skin and accidental self-injection. Use protective gloves when handling and administering the product. Wash exposed skin after use.

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. Persons developing a reaction after contact with the product should avoid handling the product (and other cephalosporins and penicillin containing products) in future.

There is no evidence of reproductive toxicity (including teratogenicity) in pigs. Laboratory studies in rats and rabbits have not shown any teratogenic, foetotoxic or maternotoxic effects. Use only according 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.
Resistance mechanism in Gram-negative organisms due to extended spectrum beta-lactamases (ESBL) and in Gram-positive organisms due to alteration of penicillin binding proteins (PBPs) may lead to cross-resistance with other beta-lactams.

Overdoses of 3x the recommended dose have been systemically well tolerated.
For reactions at the injection site, please see lesions already described at the recommended dose under section 6.

Incompatibilities:
This veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Box of one 50 ml glass vial
Box of one 100 ml glass vial
Box of one 250 ml glass vial

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.

Approved 06 April 2017