Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection
White to off-white resuspendable suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Pigs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in animals which are known to be hypersensitive to cephalosporin antibiotics or to other β-lactam antibiotics, or to any of the excipients.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

Cobactan LA 7.5% w/v suspension for injection for swine selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, 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 (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) 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 in the SPC, may increase the prevalence of such 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.

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 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 preparations.

2. Handle this product with great care to avoid exposure by accidental contact with the skin and accidental self-injection. 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.

4.6 Adverse reactions (frequency and seriousness)

Pain at injection was very commonly observed in a clinical study. Limited macroscopic lesions (2x5cm area) were commonly 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 reactions 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)

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

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).
Shake the vial well before using.
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, automatic syringe equipment, or a suitable draw-off needle, should be used to avoid excessive puncturing of the closure.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Overdoses of 3x the recommended dose have been systemically well tolerated.

4.11 Withdrawal Period(s)

Pigs (meat and offal): 7 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: cephalosporins and related substances
ATCvet code: QJ01DE90

5.1 Pharmacodynamic properties

Cefquinome is an antibacterial of the cephalosporin group which acts by inhibition of cell wall synthesis. It is bactericidal, is time dependant and is characterised by its broad therapeutic spectrum of activity. As a fourth generation cephalosporin, it combines high cellular penetration and a high stability against beta-lactamases which predict a lower probability for selection. In contrast to cephalosporins of previous generations, cefquinome is not hydrolysed by chromosomally–encoded cephalosporinases of the Amp-C type or by plasmid mediated cephalosporinases of some enterobacterial species. 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.

In vitro activity has been demonstrated against *Actinobacillus pleuropneumoniae, Haemophilus parasuis* and *Pasteurella multocida*.
A total of 178 *Actinobacillus pleuropneumoniae,* 43 *Haemophilus parasuis* and 185 *Pasteurella multocida* isolated between 2004 and 2010 from the respiratory tract of diseased pigs across Europe were investigated.
Actinobacillus pleuropneumoniae and *Haemophilus parasuis* have a MIC_{90} of 0.032 µg/ml. The MIC_{90} for *Pasteurella multocida* is 0.063 µg/ml.

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

5.2 Pharmacokinetic properties

After intramuscular administration of Cobactan LA 7.5% w/v at the recommended dose maximum serum concentrations (C_{max}) in the range of 0.86 µg/ml and 0.88 µg/ml are reached after approximately 1 hour. Terminal half life is around 9 hours.
Cefquinome binds poorly to plasma proteins in pigs (about 14%). It is excreted mainly via the urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate
Triglycerides medium-chain

6.2 Incompatibilities

Do not mix with other veterinary medicinal products

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after first opening of the container: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

50 ml, 100 ml and 250 ml type II glass vials sealed with chlorobutyl rubber stoppers

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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/266/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th June 2012

Date of latest renewal: 24th March 2017

10 DATE OF REVISION OF THE TEXT

March 2017