Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a 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

Cattle.

4.2 Indications for use, specifying the target species

For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni* sensitive to cefquinome.

4.3 Contraindications

Do not use in 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Cobactan 7.5% selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) which may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, Cobactan 7.5% 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 7.5% should only be used based on susceptibility testing. Cobactan 7.5% 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 limited to ongoing disease outbreaks according to the approved conditions of use.

Relapses of respiratory signs may be seen in treated animals 1-2 weeks after administration of the last dose. In such cases other treatment options should be considered.

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)

Subcutaneous injection of the medicinal product induces an inflammatory tissue reaction at the injection site. The lesions caused by the injection of up to 10 ml may persist for at least 28 days after the last dose has been administered. Fibrous plaques up to 15.0 x 5.5 x 0.2 cm may still be present. Application into the underlying muscle may result in muscle degeneration.

4.7 Use during pregnancy, lactation or lay

There is no evidence of reproductive toxicity (incl. teratogenicity) in cattle. 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.

4.9 Amounts to be administered and administration route

For subcutaneous administration: two injections with 48 hours interval.
2.5 mg cefquinome/kg bodyweight (equivalent to 1 ml of Cobactan LA 7.5% w/v /30 kg bodyweight)
To ensure the correct dosage and to avoid possible underdosing, body weight should be determined as accurately as possible.
Shake the vial well before using.
It is recommended to divide the dose so that no more than 10 ml of the product are injected at one site. Do not use the same injection site more than once during a course of treatment.

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

Overdoses of 3 times the recommended dose in cattle have been systemically well tolerated. For reactions at the injection site, please see lesions already described at the recommended dose under section 4.6.

4.11 Withdrawal Period(s)

Meat and offal: 13 days.

Do not use in dairy cows producing milk for human consumption (during lactation or the dry period). Do not use within two months prior to first calving in heifers intended for the production of milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: other beta-lactam antibacterials
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 and 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 *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni.*

A total of 197 *Pasteurella multocida*, 107 *Mannheimia haemolytica* and 33 *Histophilus somni* isolated between 2000 and 2006 from the respiratory tract of diseased cattle in Belgium, France, Germany, Italy, Ireland, the Netherlands, Spain and the United Kingdom were investigated.

The MIC 90 for *Pasteurella multocida* and *Mannheimia haemolytica* strains was 0.032 µg/ml, and 0.004 µg/ml for *Histophilus somni* strains. The period of time that plasma concentrations were above MIC (T > MIC) for *Pasteurella multocida* and *Mannheimia haemolytica* (MIC 90 = 0.032 µg/ml) was 80.7% of the treatment interval or 38.7 hours.

5.2 Pharmacokinetic properties

Maximum serum concentrations (C_{max}) of about 1 microgram/ml are reached after 2 to 12 hours after subcutaneous administration of the product at the recommended dose of 2.5 mg/kg.
Cefquinome is < 5 % protein bound and excreted unchanged in the urine. In calves, 90% of the dose are recovered in urine and about 5% from faeces.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate
Triglycerides medium-chain

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months.
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

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

Box of one 50ml 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,
Citywest Road,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10996/201/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th May 2011

10 DATE OF REVISION OF THE TEXT

June 2013