Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan 2.5% w/v Suspension for Injection.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance	
Cefquinome sulfate equivalent to Cefquinome	25 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.

A milky-white to slightly brownish suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs.

4.2 Indications for use, specifying the target species

For the treatment of bacterial infections in cattle and pigs caused by the Gram positive and Gram negative microorganisms sensitive to Cefquinome.

Cattle:

1. Respiratory disease caused by *Pasteurella multocida* and *Mannheimia haemolytica.*
2. Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot).
3. Acute *E.coli* mastitis with signs of systemic involvement.
4. *E.coli* septicaemia in calves.

Pigs:

1. 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.
2. Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *E.coli, Staphylococcu*s spp., *Streptococcus* spp., *Corynebacterium* spp. and other Cefquinome sensitive organisms.

4.3 Contraindications

Do not use in animals known to be hypersensitive to the active substance.
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 known.

4.5 Special precautions for use

Special precaution for use in animals

Cobactan 2.5 % w/v 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 2.5 % w/v 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 2.5 % w/v should only be used based on susceptibility testing.
Cobactan 2.5 % w/v 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, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure.
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.

4.6 Adverse reactions (frequency and seriousness)

Use of the product may result in localised tissue reaction. Tissue lesions are repaired 15 days after the last administration of the product.

Hypersensitivity reactions can occur rarely.

4.7 Use during pregnancy, lactation or lay

In clinical studies no abortions or abnormalities of calves were observed among pregnant cows treated with cefquinome.

Laboratory studies in the rat and the rabbit have not produced any evidence of an effect on fertility nor a teratogenic effect.

No information is available on the use of cefquinome in pregnant sows or gilts.

4.8 Interaction with other medicinal products and other forms of interaction

There is a cross sensitivity between the various cephalosporins and other β lactam antibiotics.

4.9 Amounts to be administered and administration route

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by *Pasteurella multocida* and *Mannheimia haemolytica*	1mg Cefquinome/kg bw (2ml/50kg bw)	Daily for 3-5 consecutive days
	Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1mg Cefquinome/kg bw (2ml/50kg bw)	Daily for 3-5 consecutive days
	Acute *E.coli* Mastitis with signs of systemic involvement	1mg Cefquinome/kg bw (2ml/50kg bw)	Daily for 2 consecutive days
Calves	*E.coli* septicaemia	2 mg Cefquinome/kg bw (4ml/50kg bw)	Daily for 3-5 consecutive days
Pigs	Respiratory infections	1-2mg Cefquinome/kg bw (equivalent to 1-2 ml per 25kg bw)	Daily for 3 consecutive days
	Mastitis-Metritis-Agalactia	2 mg Cefquinome/kg bw (2 ml/25 kg bw)	Daily for 2 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.

Shake the vial before using.

The product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry sterile needle and syringe.

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

Overdoses up to 10 mg/kg bw have been well tolerated in cattle and pigs.

4.11 Withdrawal Period(s)

Cattle:
Meat and offal: 5 days
Milk: 24 hours

Calves:
Meat and offal: 4 days

Pigs:
Meat and offal: 3 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use - Fourth-generation cephalosporins.
ATC vet code: QJ01DE90

5.1 Pharmacodynamic properties

Cefquinome is an antibacterial drug of the cephalosporin group which acts by inhibition of the cell wall synthesis. It is characterised by its broad therapeutic spectrum of activity and a high stability against penicillinases and beta-lactamases. In vitro activity has been demonstrated against common Gram positive and Gram negative bacteria including *Escherichia coli*., *Citrobacter* spp., *Klebsiella* spp., *Pasteurella* spp., *Proteus* spp., *Salmonella* spp., *Serratia marcenscens*, *Haemophilus somnus*, *Actinomyces pyogenes*, *Bacillus* spp., *Corynebacterium* spp., *Staphylococcus* spp., *Streptococcus* spp., *Clostridium* spp., *Fusobacterium* spp., *Prevotella* spp. *(Bacteroides* spp.), *Actinobacillus* spp. and *Erysipelothrix rhusiopathiae.*

5.2 Pharmacokinetic properties

In cattle peak serum concentrations of about 2 µg/ml are reached within 1.5-2 hours after intramuscular or subcutaneous administration. Cefquinome has a relatively short half-life (2.5 hours), is <5% protein bound and excreted unchanged in the urine. Cefquinome is not absorbed after oral administration.

In pigs at double the cattle dosage, maximum serum concentrations of 4.8 µg/ml on average are measured within 20 to 60 minutes after intramuscular injection. The average half life in this species is about 9 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl oleate

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Protect from light.

6.5 Nature and composition of immediate packaging

50 ml and 100 ml Type II Ph. Eur. colourless glass vials with epichlorhydrin rubber stoppers and aluminium overseals.

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 Ltd.,
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/104/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th August 2011

10 DATE OF REVISION OF THE TEXT

March 2012