

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cobactan 25 mg/ml suspension for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

25 mg Cefquinome (as cefquinome sulfate)

Excipients:

Qualitative composition of excipients and other constituents
Ethyl oleate

A milky-white to slightly brownish suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs.

3.2 Indications for use for each 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*, *Staphylococcus* spp., *Streptococcus* spp., *Corynebacterium* spp. and other Cefquinome sensitive organisms.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipient(s).

Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product 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, the veterinary medicinal product 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, the veterinary medicinal product should only be used based on susceptibility testing.

The veterinary medicinal product 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. People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product.
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 package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, pigs:

Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site reaction ¹

¹ Tissue lesions are repaired 15 days after the last administration of the product.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Intramuscular use.

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

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle:

Meat and offal: 5 days.

Milk: 24 hours.

Calves:

Meat and offal: 4 days.

Pigs:

Meat and offal: 3 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01DE90

4.2 Pharmacodynamics

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 marcescens*, *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*.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

Do not store above 25°C.

Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box containing one 50 ml or 100 ml Type II Ph. Eur. colourless glass vials with epichlorhydrin rubber stoppers and aluminium overseals.

Cardboard box of one 50 ml glass bottle.

Cardboard box of one 100 ml glass bottle.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/104/001

8. DATE OF FIRST AUTHORISATION

20/09/1995

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

30/04/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).