1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substance:
Cefquinome (as sulfate) 25 mg
Excipient(s):
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection.
White to slightly yellowish suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

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

Calves:
E.coli septicaemia in calves.

Pigs:
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.
Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *E.coli*, *Staphylococcus* spp., *Streptococcus* spp. and other cefquinome sensitive organisms.

Piglets:
Reduction of mortality in cases of meningitis caused by *Streptococcus suis*.
For the treatment of:
Arthritis caused by *Streptococcus* spp., *E. coli* and other cefquinome-sensitive organisms.
Epidermitis (mild or moderate lesions) caused by *Staphylococcus hyicus*.

4.3 Contraindications

Do not use in case of hypersensitivity to β-lactam antibiotics, or to any of the excipients.
Do not administer to animals less than 1.25 kg body weight.
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

In case of occurrence of allergic reaction, the treatment should be withdrawn.

The use of cefquinome should be restricted to appropriate use according to the labelled indications in the target animal species.

Inappropriate use of the product may increase the prevalence of bacteria resistant to cefquinome and may decrease the effectiveness of treatment with other beta lactam antibiotics, due to the potential for cross resistance.

The 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 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 product should only be used based on susceptibility testing.

The product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programs. 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

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 sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
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. Care should be taken to avoid accidental injection and contact with the skin. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Use of the veterinary medicinal product may result in localised tissue reaction. Tissue lesions are repaired 15 days after the last administration of the veterinary medicinal product.
Hypersensitivity reactions to cephalosporins occur rarely.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reactions)
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rat and rabbit have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects. The safety of the product has not been assessed in cow and sow during pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Due to an undesirable pharmacodynamic interaction, do not use cefquinome simultaneously with pharmaceuticals acting bacteriostatically.

4.9 Amounts to be administered and administration route

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by *Pasteurella multocida* and*M. haemolytica*	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
	Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)		
	Acute *E. coli* mastitis with signs of systemic involvement	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 2 consecutive days
Calves	*E. coli* septicaemia	2 mg cefquinome/kg bw (4 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
Pigs	Respiratory disease	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 3 consecutive days
	MMA	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 2 consecutive days.
Piglets	Meningitis Arthritis Epidermitis	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 5 consecutive days

All treatments to be given by intramuscular injection. Studies have indicated the advisability of giving second and subsequent injections at different injection sites. The preferred injection site is in the muscular tissue of the mid-neck.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

Before use shake the bottle for a minute or until the product appears adequately resuspended.

The veterinary medicinal product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry sterile needle and syringe. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes, for example when treating piglets. When treating groups of animals, use a draw-off needle.

The rubber stopper of the 100 ml vial may be safely punctured up to 25 times and the rubber stopper of the 250 ml vial may be safely punctured up to 50 times. The user should choose the most appropriate vial size according to the target species and body weight category of animals to be treated.

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

Overdoses of 20 mg/kg/day in cattle and 10 mg/kg/day in pigs and piglets have been well tolerated.

4.11 Withdrawal period(s)

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

The antibacterial drug cefquinome is a broad-spectrum cephalosporin of the fourth-generation which acts by inhibition of the cell wall synthesis. It is bactericidal and 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 bovine strains of *Pasteurella multocida, Mannheimia haemolytica, Escherichia coli* and anaerobes *(Bacteroides* spp*., Fusobacterium* spp*.)* and against porcine strains of *Streptococcus* spp., *Staphylococcus* spp., *Pasteurella multocida, Haemophilus parasuis, Actinobacillus pleuropneumoniae* and *Escherichia coli.*

According to susceptibility data from European countries, bovine strains of *Pasteurella multocida, Mannheimia haemolytica* and *non-enteric Escherichia coli* as well as porcine strains of *Pasteurella multocida, Actinobacillus pleuropneumoniae, Haemophilus parasuis, Streptococcus suis* and *Escherichia coli* were found to be highly susceptible to cefquinome. Porcine strains of β-haemolytic Streptococci, *Staphylococcus hyicus* and *Staphylococcus aureus* showed moderate susceptibility.

Cefquinome as a fourth generation cephalosporin combines high cellular penetration and ß-lactamase stability. 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. However, some extended spectrum betalactamases (ESBL) can hydrolyse cefquinome and cephalosporins of other generations. The potential for resistance development against cefquinome is rather low. High-level resistance to cefquinome would require the coincidence of two genetic modifications, i.e. hyperproduction of specific ß-lactamases as well as decreased membrane permeability.

5.2 Pharmacokinetic particulars

In cattle peak serum concentrations of about 2 µg/ml are reached within 1.5-2 hours after intramuscular administration at the dose of 1 mg/kg. Cefquinome has a relatively short terminal half-life (2.5 hours), is < 5 % protein bound and excreted unchanged in the urine.
In pigs or piglets, at 2 mg/kg dosage, maximum serum concentrations of around 5 µg/ml are measured within 15 to 60 minutes after intramuscular injection. The average half-life is about 9 hours.
Cefquinome binds poorly to plasma proteins and therefore penetrates into the cerebrospinal fluid (CSF) and the synovial fluid in pigs. The concentration profile is similar between the synovial fluid and the plasma. The concentrations reached in the CSF 12 hours after treatment are similar to those in plasma.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethyl oleate

6.2 Major 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: 3 years
Shelf-life after first opening of the immediate packaging: 28 days

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Carton with 1, 6 or 12 colourless Type II glass vials containing 100 ml or 1 or 6 colourless Type II glass vials containing 250 ml. Each vial is closed with a fluorinated bromobutyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

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

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

7 MARKETING AUTHORISATION HOLDER

Emdoka bvba
John Lijsenstraat 16
B-2321 Hoogstraten
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10534/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7th December 2012
Date of last renewal: 16th February 2018

10 DATE OF REVISION OF THE TEXT

April 2018