CEFANIL INJECTION
(Cefquinome Sulfate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFANIL INJECTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Cefquinome (as Sulfate) …... 25mg

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL INFORMATION

4.1. Target species

Cattle

4.2. Indications for use specifying the target species

For the treatment of bacterial infections in cattle 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.

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

Not Reported

4.5. Special precautions for use

Special precautions for safe use in the target species:

In case of occurrence of allergic reaction, the treatment should be withdrawn.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 Beta lactamases (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 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 and 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 veterinary medicinal products and other forms of interaction

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

4.9. Dosage and administration route

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by Pasteurella multocida andM. Haemolytica Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 or 5 consecutive days
	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	2mg cefquinome/kg bw (4 ml/50 kg bw)	Once daily for 3 or 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. 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 have been well tolerated.

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antibacterials for systemic use, fourth-generation cephalosporins
ATC vet code: **QJ01DE90**

5.1. Pharmacodynamics 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 information

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. Cefquinome binds poorly to plasma proteins and therefore penetrates into the cerebrospinal fluid (CSF) and the synovial fluid. 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 INFORMATION

6.1 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 container: use within 28 days, do not store.

6.4. Special precautions for storage

Store below 25°C.
Protect from light and moisture.
Shake well before use.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.5. Nature and composition of primary conditioning

Cardboard box with glass injection vial (s).
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 50ml Vial

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS
UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.
Plots No. 136-138, Sector-15,
Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 081319

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 15-08-2016

10. DATE OF REVISION OF THE TEXT

17-02-2025