SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Naxcel 200 mg/ml suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Ceftiofur (as crystalline free acid) 200 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Opaque white to light brown suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

Treatment of acute interdigital necrobacillosis in cattle also known as panaritium or foot rot.
Treatment of acute post-partum (puerperal) metritis in cattle, in cases where treatment with another antimicrobial has failed.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to other beta-lactam antibiotics or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
For systemically-administered broad-spectrum cephalosporins (3rd and 4th generation, such as ceftiofur), it should be reflected that these are to be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to less critical antimicrobials. Increased use, including use of the product deviating from the

instructions given in the Summary of Product Characteristics (SPC), may increase the prevalence of bacteria resistant to ceftiofur. Official, national and regional antimicrobial policies should be taken into account when the product is used.

Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing. When considering the treatment strategy, it is appropriate to consider improvement of the herd management practice and use supporting treatment with suitable local products (e.g. disinfectants).
Do not use as prophylaxis in cases of retained placenta.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillins and cephalosporins such as ceftiofur may cause hypersensitivity in people and in animals following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.
People with known hypersensitivity to penicillins and cephalosporins should avoid contact with the veterinary medicinal product.
Avoid contact with skin or eyes. In the event of contact, wash with clean water.
If you develop symptoms following exposure such as a skin rash or persistent eye irritation, 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

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1], Injection site pain[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis, Sudden death[3]

[1]Visible two days after injection in about two thirds of treated animals and resolving within a maximum of 23 days.
[2]Mild to moderate in the initial days following injection.
[3]Following accidental intra-vascular administration or anaphylaxis.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in mice have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Laboratory studies in rats have shown no evidence of teratogenic effects but maternotoxic (soft faeces) and foetotoxic (reduced foetal weight) effects were observed. No effects on the reproductive performance were observed. No specific studies have been conducted in pregnant cows and breeding cattle. Use only according to the benefit-risk assessment by the responsible veterinarian.
This veterinary medicinal product can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

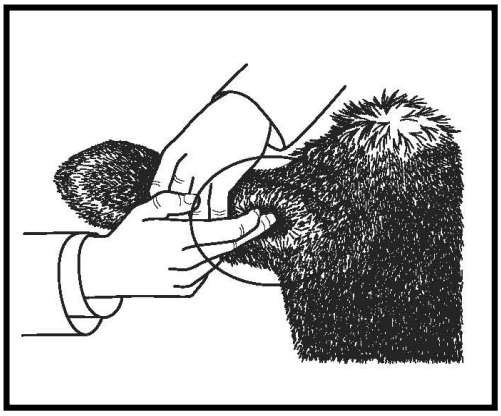
4.9 Amounts to be administered and administration route

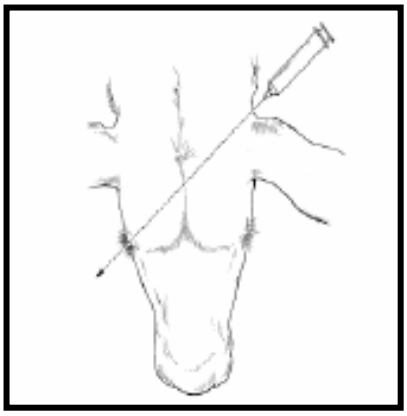
Single subcutaneous injection of 6.6 mg ceftiofur/kg body weight (equivalent to 1 ml of the veterinary medicinal product per 30 kg body weight) administered at the base of the ear. To ensure a correct dosage, body weight should be determined as accurately as possible. It is recommended to limit injection volumes to a maximum of 30 ml per injection site.

Shake the bottle vigorously for 30 seconds, or until all visual settlement has been resuspended.

Base of the ear administration:
• Administer in the posterior part of the ear base (see Figure 1).
• Hold the syringe and insert the needle behind the animal's ear so the needle and syringe point in the direction of an imaginary line that would pass through the head toward the animal's opposite eye (see Figure 2).
• Take appropriate precautions to avoid intra-arterial or intravenous injection, such as restraining appropriately the animal (chute or head restraint for example) and using appropriate needles [1 inch (2.54 cm) long, 16 gauge].

Figure 1. Injection location for the subcutaneous administration of the veterinary medicinal product at the posterior aspect of the ear where it attaches to the head (base of ear).		Figure 2. Subcutaneous administration of the veterinary medicinal product at the posterior aspect of the ear where it attaches to the head (base of ear). Diagram of the head showing the direction for the base of the ear injections administered toward the animal's opposite eye.





If clinical signs have not improved 48 hours after treatment, the diagnosis and treatment of the condition should be re-evaluated.

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

In cattle, although the veterinary medicinal product has not been specifically tested for overdoses, no signs of systemic toxicity related to ceftiofur have been observed following 55 mg/kg parenteral daily overdoses of ceftiofur sodium for five days.

4.11 Withdrawal period(s)

Meat and offal: 9 days.
Milk: Zero days.
It is essential that the veterinary medicinal product is only administered subcutaneously at the base of ear location in non-edible tissue, as described in section 4.9, in order to comply with the meat withdrawal period.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, third-generation cephalosporins.

ATCvet code: QJ01DD90

5.1 Pharmacodynamic properties

Ceftiofur is a third-generation cephalosporin antibiotic, which is active against many Gram-positive and Gram-negative pathogens. Ceftiofur inhibits the bacterial cell wall synthesis, thereby exerting bactericidal properties.

In cattle, ceftiofur is active against the following micro-organisms which are involved in acute post-partum (puerperal) metritis: *Escherichia coli*, *Arcanobacterium pyogenes* and *Fusobacterium necrophorum*; and interdigital necrobacillosis: *Bacteroides* spp., *Fusobacterium necrophorum*, *Porphyromonas* spp. and *Prevotella* spp.

Desfuroylceftiofur is the principal active metabolite. It has an antimicrobial activity similar to that of ceftiofur against the target pathogens.

5.2 Pharmacokinetic particulars

Ceftiofur is well absorbed in cattle following base of the ear injection. After administration, ceftiofur is quickly metabolised to desfuroylceftiofur, the principal active metabolite. Protein binding of ceftiofur and its major metabolite is high, approximately 70% – 90%. One hour after a single administration, plasma concentrations are greater than 1 µg/ml. Maximum concentrations in plasma (about 5 µg/ml) occurred from 12 hours following administration. Total plasma concentrations above 0.2 µg/ml and 1 µg/ml of ceftiofur and its active metabolites are maintained for at least 7 and 4 days, respectively.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Triglycerides, medium chain
Cottonseed oil.

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: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

Cardboard box with one type I glass vial of 100 ml with a chlorobutyl-isoprene rubber stopper and an aluminium cap.

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

Medicines should not be disposed of via wastewater.

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5041

9. DATE OF FIRST AUTHORISATION

18 October 2009

10. DATE OF REVISION OF THE TEXT

December 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 08 December 2023