PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Naxcel 200 mg/ml suspension for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur 200 mg/ml.

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.
Milk: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5041

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE VIAL OF 100 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Naxcel 200 mg/ml suspension for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur 200 mg/ml.

100 ml

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

SC

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.
Milk: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Naxcel 200 mg/ml suspension for injection for cattle

2. COMPOSITION

One ml contains:

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

Opaque white to light brown suspension.

3. TARGET SPECIES

Cattle.

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

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

6. SPECIAL WARNINGS

Special precautions for safe use in the target species:
Whenever possible, the veterinary medicinal product should only be used based on susceptibility testing.

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 above, 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.
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.

Pregnancy and fertility:
No specific studies have been conducted in pregnant cows or in breeding cattle. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:
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.

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

7. ADVERSE EVENTS

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder or the local representative of the marketing authorisation holder

using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

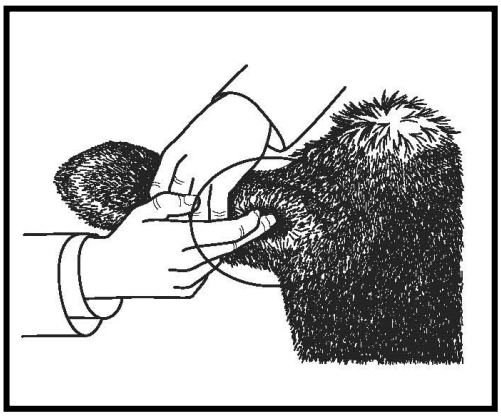
Single subcutaneous injection of 6.6 mg ceftiofur/kg body weight (equivalent to 1 ml of the veterinary medicinal product per 30 kg body weight) administered at the base of the ear.

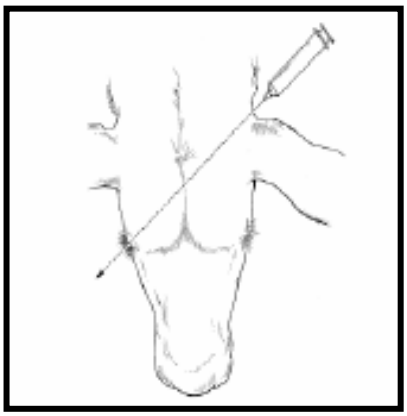
9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIODS

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, in order to comply with the meat withdrawal period.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 ˚C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 42058/5041

Cardboard box containing 1 glass vial of 100 ml.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey, KT22 7LP
UK
Tel: +44 (0) 345 300 8034

Marketing authorisation holder and manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Belgium

Approved 14 May 2024