PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Naxcel 100 mg/ml suspension for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur 100 mg/ml.

3. PACKAGE SIZE

100 ml
50 ml

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 71 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 NUMBER

Vm 42058/5040

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 100 mg/ml suspension for injection.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur 100 mg/ml.

100 ml

3. TARGET SPECIES

Pigs.

4. ROUTES OF ADMINISTRATION

IM

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 71 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 PRODUCTS 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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS VIAL OF 50 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Naxcel

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Ceftiofur 100 mg/ml.

50 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use by…

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Naxcel 100 mg/ml suspension for injection for pigs

2. COMPOSITION

One ml contains:

Active substance:
Ceftiofur (as crystalline free acid) 100 mg.

Opaque white to light brown suspension.

3. TARGET SPECIES

Pigs.

4. INDICATIONS FOR USE

Treatment of bacterial respiratory disease associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis* and *Streptococcus suis*.
Treatment of septicaemia, polyarthritis or polyserositis associated with *Streptococcus suis* infection.

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).

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 or lactating sows, or in breeding pigs. Use only according to the benefit-risk assessment by the responsible veterinarian.

Overdose:
Owing to the low toxicity of ceftiofur in pigs overdoses do not typically lead to any clinical signs, other than transient local swellings as described in section 7 (Adverse events).

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

7. ADVERSE EVENTS

Pigs:

Very common (>1 animal / 10 animals treated):
Injection site swelling[1], Injection site skin discolouration[2,3], Injection site blister[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reaction

[1]Transient; following intramuscular injection.
[2]Have been observed for up to 42 days after injection and resolution has been observed at 56 days post injection.
[3]Less than 6 cm^2.

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

Intramuscular use.

Dose of 5 mg ceftiofur/kg body weight (equivalent to 1 ml of the veterinary medicinal product per 20 kg body weight) administered once in the neck by intramuscular injection.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIODS

Meat and offal: 71 days.

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 NUMBERS AND PACK SIZES

Vm 42058/5040

Cardboard box containing 1 glass vial of 50 ml or 100 ml.

Not all pack sizes may be marketed.

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

POM-V
Veterinary medicinal product subject to prescription

For animal treatment only.