SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Naxcel 100 mg/ml suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Ceftiofur (as crystalline free acid) 100 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

Pigs.

4.2 Indications for use, specifying the target species

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.

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).

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)

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 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 revealed no teratogenic effects but maternotoxic (soft faeces) and foetotoxic (reduced foetal weight) effects were observed. No effects on the reproductive performance were observed. No 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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

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.
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.

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

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 4.6 (Adverse reactions).

4.11 Withdrawal period(s)

Meat and offal: 71 days.

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.

Ceftiofur is particularly active against the following target pathogens causing respiratory and other diseases in pigs: *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis* and *Streptococcus suis*. *Bordetella bronchiseptica* is inherently insensitive to ceftiofur *in vitro*.

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

At the recommended therapeutic dose, concentrations in plasma were higher than the MIC_{90} values (<0.2 µg/ml) for the target bacteria isolated in clinical studies, for at least 158 hours.

5.2 Pharmacokinetic particulars

After administration, ceftiofur is quickly metabolised to desfuroylceftiofur, the principal active metabolite.

Protein binding of ceftiofur and its major metabolite is approximately 70%. One hour after a single administration, plasma concentrations are above 1 µg/ml.
Maximum concentrations in plasma (4.2 ± 0.9 µg/ml) are reached at approximately 22 hours after administration. Plasma concentrations above 0.2 µg/ml of ceftiofur and its metabolite are maintained for an appropriate period of time.
Approximately 60% and 15% of the dose are excreted in the urine and faeces, respectively, within 10 days after administration.

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 50 ml or 100 ml with a chlorobutyl-isoprene rubber stopper and an aluminium cap.

Not all pack sizes may be marketed.

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 42058/5040

9. DATE OF FIRST AUTHORISATION

19 May 2005

10. DATE OF REVISION OF THE TEXT

December 2023

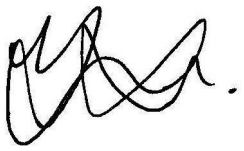
PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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: 23 January 2024