ANNEX I

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(s):
Ceftiofur (as crystalline free acid) 100 mg

For a 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 ceftiofur or other β-lactam antibiotics, or to any of the excipients.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals
For systemically administered broad spectrum cephalosporins (3rd and 4thgeneration, 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 more narrow spectrum antimicrobials. Increased use, including use of the product deviating from the instructions given in the 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, cephalosporins 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 this 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.

4.6 Adverse reactions (frequency and seriousness)

Occasionally, transient local swelling may occur following intramuscular injection.
Mild tissue reactions at the injection site, such as small areas (less than 6 cm^2) of discolouration and small cysts have been observed for up to 42 days after injection. Resolution has been observed at 56 days post-injection. In very rare cases anaphylactic type reactions may occur following administration of the product.

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 fetal weight) effects were observed. No effects on the reproductive performance were observed in both species. 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.

5 mg ceftiofur/kg body weight (equivalent to 1 ml of NAXCEL 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 accurately determined to avoid under-dosing.
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 (undesirable effects).

4.11 Withdrawal period(s)

Meat and offal: 71 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: 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

Oily vehicle (vegetable origin):
Triglycerides, medium chain
Cottonseed oil.

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: 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 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

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

7. MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

8. MARKETING AUTHORISATION NUMBER (S)

EU/2/05/053/001
EU/2/05/053/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19/05/2005
Date of last renewal: 26/05/2010

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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 a 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 ceftiofur or other beta-lactam antibiotics, or to any of the excipients.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals
For systemically administered broad spectrum cephalosporins (3^{rd} and 4^{th} 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 other antimicrobials. Increased use, including use of the product deviating from the instructions given in the 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, cephalosporins 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 case 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 this 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 serious reactions and require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

Visible swellings have been noted at the injection site in about two thirds of treated animals, two days after injection in field conditions. These reactions will resolve within a maximum of 23 days. Injection site swellings may result in mild to moderate pain in some animals in the initial days following injection.

In very rare cases (i.e. in less than 1 out of 10,000 animals), sudden death has been reported following administration of the product. In such cases, death has been attributed to intra-vascular administration of the product or anaphylaxis.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
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 in both species. No specific studies have been conducted in pregnant cows. Use only according to the benefit/risk assessment by the responsible veterinarian.

Lactation:
This veterinary medicinal product can be used during lactation.

Fertility:
No specific studies have been conducted in breeding cattle. 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

Single subcutaneous injection of 6.6 mg ceftiofur/kg body weight (equivalent to 1 ml of NAXCEL per 30 kg body weight) administered at the base of the ear.
To ensure a correct dosage, body weight should be accurately determined to avoid under-dosing.
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 2).
• 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 1).
• Take appropriate precautions to avoid intra-arterial or intravenous injection.

Figure 1. Subcutaneous administration of NAXCEL at the posterior aspect of the ear where it attaches to the head (base of ear)

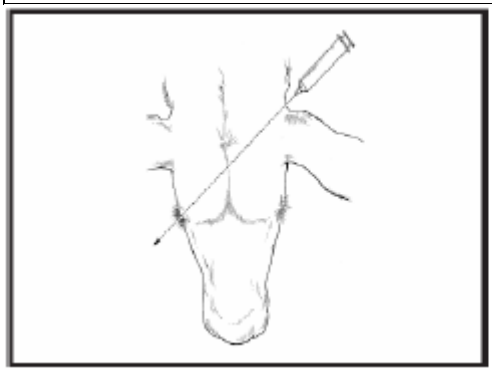
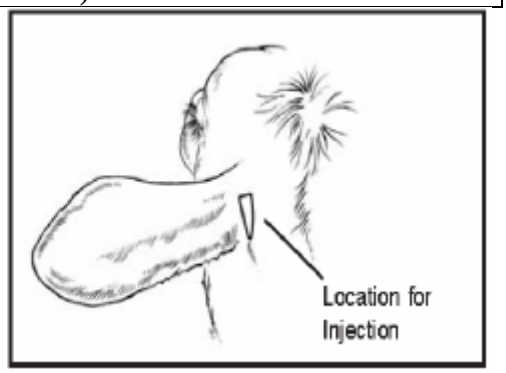


Figure 2. Injection location for the subcutaneous administration of NAXCEL at the posterior aspect of the ear where it attaches to the head (base of ear)



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 NAXCEL 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 NAXCEL 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: 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

Oily vehicle (vegetable origin):
Triglycerides, medium chain
Cottonseed oil.

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 vial: 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

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

7. MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/053/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08/10/2009
Date of last renewal: 26/05/2010

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

D. STATEMENT OF THE MRLs

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Pfizer N.V/S.A
Rijksweg 12
B-2870 Puurs
Belgium

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable.

D. STATEMENT OF THE MRLs

The active substance in Naxcel is included in table 1 of the annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmaco-logically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
Ceftiofur	Sum of all residues retaining the betalactam structure expressed as desfuroyl-ceftiofur	All mammalian food producing species	1,000 µg/kg 2,000 µg/kg 2,000 µg/kg 6,000 µg/kg 100 µg/kg	Muscle Fat Liver Kidney Milk	For porcine species the fat MRL relates to 'skin and fat in natural proportions'.	Anti-infectious agents/Antibiotics

The excipients, listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE INSERT

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NAXCEL 100 mg/ml suspension for injection for pigs
Ceftiofur

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

Excipient:
Oily vehicle (vegetable origin).

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
50 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

5 mg ceftiofur/kg body weight (equivalent to 1 ml of NAXCEL 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 accurately determined to avoid under-dosing.
It is recommended to limit injection volumes to a maximum of 4 ml.

8 WITHDRAWAL PERIOD

Meat and offal: 71 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package insert before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/053/001 (100 ml)
EU/2/05/053/002 (50 ml)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL – 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NAXCEL 100 mg/ml suspension for injection for pigs
Ceftiofur

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as crystalline free acid) 100 mg/ml,
Oily vehicle (vegetable origin).

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5 mg ceftiofur/kg body weight (1 ml / 20 kg body weight).
Shake bottle vigorously.
It is recommended to limit injection volumes to a maximum of 4 ml.

8. WITHDRAWAL PERIOD

Meat and offal: 71 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by …..*<leave space for the date to be inserted>*

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12 SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS , IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/053/001

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE

VIAL – 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NAXCEL 100 mg/ml suspension for injection for pigs

Ceftiofur

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ceftiofur 100 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5 mg ceftiofur/kg (1 ml / 20 kg).
Shake bottle vigorously.
It is recommended to limit injection volumes to a maximum of 4 ml.
Read the package leaflet before use.

5 WITHDRAWAL PERIOD

Meat and offal: 71 days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by .....*<leave space for the date to be inserted>*

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NAXCEL 200 mg/ml suspension for injection for cattle
Ceftiofur

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

Excipient:
Oily vehicle (vegetable origin).

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Treatment of acute interdigital necrobacillosis (*Panaritium*, foot rot).

Treatment of acute post-partum (puerperal) metritis in cases where treatment with another antimicrobial has failed

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Single subcutaneous injection of 6.6 mg ceftiofur/kg bw (equivalent to 1 ml of NAXCEL per 30 kg bw) administered at the base of the ear.
It is recommended to limit injection volumes to a maximum of 30 ml per injection site.
Take appropriate precautions to avoid intra-arterial or intravenous injection.
Shake the bottle vigorously for 30 seconds, or until all visual settlement has been resuspended.

8. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Milk: zero days.
NAXCEL must only be administered at the base of ear location in non-edible tissue in order to comply with the withdrawal period.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by…..

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/053/003

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

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 for cattle
Ceftiofur

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as crystalline free acid) 200 mg/ml,
Oily vehicle (vegetable origin).

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle

6. METHOD AND ROUTE(S) OF ADMINISTRATION

Single subcutaneous injection of 6.6 mg ceftiofur/kg body weight (equivalent to 1 ml of NAXCEL per 30 kg body weight) administered at the base of the ear.
Shake the bottle vigorously for 30 seconds, or until all visual settlement has been resuspended.

7. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Milk: zero days.
Read the package leaflet before use.

8. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

9. EXPIRY DATE

EXP
Once broached, use by…

10. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

11. SPECIAL 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 - to be supplied only on veterinary prescription.

13. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

14. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

15. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/053/003

16. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE INSERT

NAXCEL 100 mg/ml suspension for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

Marketing authorisation holder:
Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

Manufacturer for the batch release:
Pfizer NV/SA
Rijksweg 12
B-2870 Puurs
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NAXCEL 100 mg/ml suspension for injection for pigs
Ceftiofur

3. STATEMENT OF THE ACTIVE AND OTHER INGREDIENT (S) (S)

1 ml contains:

Active substance:
Ceftiofur (as crystalline free acid) 100 mg,
Excipients:
Oily vehicle (vegetable oil).

4. INDICATION(S)

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 ceftiofur or other ß-lactam antibiotics, or to any of the excipients.

6. ADVERSE REACTIONS

Occasionally, transient local swelling may occur following intramuscular injection.

Mild tissue reactions at the injection site, such as small areas (less than 6 cm^2) of discolouration and small cysts have been observed for up to 42 days after injection. Resolution has been observed at 56 days post-injection.
In very rare cases anaphylactic type reactions may occur following administration of the product.

If you notice any other side effects, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, METHOD AND ROUTE(S) OF ADMINISTRATION

5 mg ceftiofur/kg body weight (equivalent to 1 ml of NAXCEL 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 accurately determined to avoid under-dosing.
It is recommended to limit injection volumes to a maximum of 4 ml.
Use of the product should be based on susceptibility testing and take into account official and local antimicrobial policies.

10. WITHDRAWAL PERIOD

Meat and offal: 71 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25 °C.
Shelf-life after first opening the container: 28 days.
Do not use after the expiry date stated on the label after EXP.

12. SPECIAL WARNING(S)

Special precautions for the animal:

Whenever possible, cephalosporins should only be used based on susceptibility testing.

For systemically administered broad spectrum cephalosporins (3^{rd} and 4^{th}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 more narrow spectrum 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).

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

Special precautions for people:

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 this 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. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Naxcel is available in 50 ml or 100 ml vials. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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United Kingdom
Pfizer Ltd
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PACKAGE LEAFLET
NAXCEL 200 mg/ml suspension for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Pfizer Limited
Ramsgate Road
Sandwich
Kent CT13 9NJ
United Kingdom

Manufacturer for the batch release:

Pfizer N.V/S.A
Rijksweg 12
B-2870 Puurs
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NAXCEL 200 mg/ml suspension for injection for cattle
Ceftiofur

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One ml contains:

Active substance:

Ceftiofur (as crystalline free acid) 200 mg,

Excipient(s):

Oily vehicle (vegetable origin).

4. INDICATION(S)

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 ceftiofur or other beta-lactam antibiotics, or to any of the excipients.

6. ADVERSE REACTIONS

Visible swellings have been noted at the injection site in about two thirds of treated animals, two days after injection in field conditions. These reactions will resolve within a maximum of 23 days. Injection site swellings may result in mild to moderate pain in some animals in the initial days following injection.

In very rare cases (i.e. in less than 1 out of 10,000 animals), sudden death has been reported following administration of the product. In such cases, death has been attributed to intra-vascular administration of the product or anaphylaxis.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Single subcutaneous injection of 6.6 mg ceftiofur/kg body weight (equivalent to 1 ml of NAXCEL 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 accurately determined to avoid under-dosing.
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 2).
• 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 1).
• Take appropriate precautions to avoid intra-arterial or intravenous injection.

Figure 1. Subcutaneous administration of NAXCEL at the posterior aspect of the ear where it attaches to the head (base of ear)

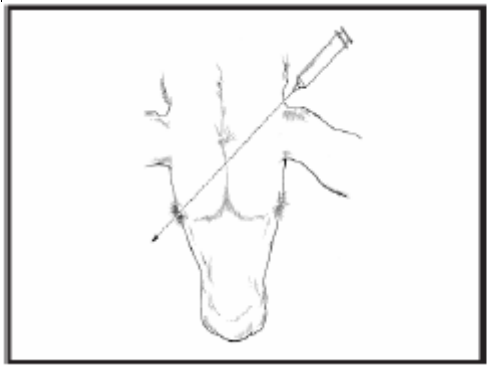
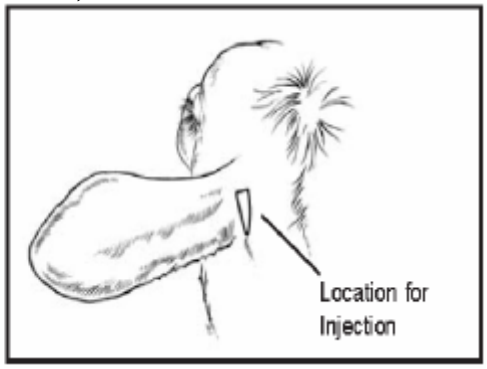


Figure 2. Injection location for the subcutaneous administration of NAXCEL at the posterior aspect of the ear where it attaches to the head (base of ear)



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

10. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Milk: zero days.

It is essential that NAXCEL 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 reach and sight of children.
Do not store above 25 °C.
Do not use after the expiry date stated on the label after EXP.
Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special precautions for the animal:

Whenever possible, cephalosporins should only be used based on susceptibility testing.

For systemically administered broad spectrum cephalosporins (3^{rd} and 4^{th} 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 other 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 case of retained placenta.

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.

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

Special precautions for people:

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.

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14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (EMA) http://www.ema.europa.eu/.

15. OTHER INFORMATION

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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