PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box: 50ml, 100 ml, 250ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle
Ceftiofur (as hydrochloride)

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride) 50 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

50ml
100ml
250ml

5. TARGET SPECIES

Pigs and Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs:
Single intramuscular injection, for 3 days

Cattle:
Single subcutaneous injection, for 3 to 5 days

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal Period:
Cattle:
Meat and offal: 5 days.
Milk: zero hours.

Pigs:
Meat and offal: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once broached, /opened, use by: _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC
Keep the vial in the outer carton in order to protect from light
This product does not contain an antimicrobial preservative.

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

Disposal: Read package leaflet

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4330

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Bottle Protector: 100 ml and 250 ml

BASE VIAL LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle
Ceftiofur (as hydrochloride)

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride) 50 mg/ml

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

100ml
250ml

5. TARGET SPECIES

Pigs and Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs:
Single intramuscular injection, for 3 days

Cattle:
Single subcutaneous injection, for 3 to 5 days

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal Period:
Cattle: Meat and offal: 5 days; Milk: zero hours.
Pigs: Meat and offal: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once broached, /opened, use by: _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC
Keep the vial in the outer carton in order to protect from light
This product does not contain an antimicrobial preservative.

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

Disposal: Read package leaflet

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 SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4330

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

EXPANDING VIAL LABEL TEXT – PAGE 1

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle
Ceftiofur (as hydrochloride)

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride) 50 mg/ml

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

100ml
250ml

5. TARGET SPECIES

Pigs and Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs:
Single intramuscular injection, for 3 days

Cattle:
Single subcutaneous injection, for 3 to 5 days

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle: Meat and offal: 5 days; Milk: zero hours.
Pigs: Meat and offal: 5 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once broached, /opened, use by: _____

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after "EXP".

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC
Keep the vial in the outer carton in order to protect from light
This product does not contain an antimicrobial preservative.

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

Disposal: Read package leaflet

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 SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4330

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

EXPANDING VIAL LABEL TEXT – PAGES 2 TO 5

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

Marketing authorisation holder and Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle
Cefenil Vet, 50mg/ml Suspension for Injection for Pigs and Cattle [FI]
Ceftiofur (as hydrochloride)

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

Ceftiofur (as hydrochloride) 50 mg/ml
A white to yellowish coloured oily suspension.

4. INDICATION(S)

Infections associated with bacteria sensitive to ceftiofur:

In Pigs:
For the treatment of bacterial respiratory disease associated with *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Streptococcus suis*.

In Cattle:
For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni.*
For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with *Fusobacterium necrophorum* and *Porphyromonas asaccharolytica (* previously *Bacteroides melaninogenicus)*.
For treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Trueperella pyogenes* (previously *Arcanobacterium pyogenes)* and *Fusobacterium necrophorum*. The indication is restricted to cases where treatment with another antimicrobial has failed.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance, to other β-lactam antibiotics or to any of the excipients.
Do not use in case of known resistance to other cephalosporins or β-lactam antibiotics
Do not use intravenously.

Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans

6. ADVERSE REACTIONS

In cattle, mild inflammatory reactions such as hardness at the injection site have been observed in some animals. Clinical resolution is reached in most animals by 21 days after injection.

In pigs, mild reactions at the injection site, such as discoloration of the fascia or fat, have been observed in some animals for up to 20 days after injection.

Hypersensitivity reactions unrelated to dose can occur. Allergic reactions (e.g. skin reactions, anaphylaxis) may occasionally occur. If an allergic reaction occurs, the treatment should be withdrawn.

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

7. TARGET SPECIES

Pigs and Cattle

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

Cattle:
Respiratory disease: 1 mg Ceftiofur /kg bw/day for 3 to 5 days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
Acute interdigital necrobacillosis: 1 mg/kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
Acute post-partum metritis within 10 days after calving: 1 mg/kg bw/day for 5 consecutive days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.

Pigs:
3 mg Ceftiofur /kg bw/day for 3 days via intramuscular route, i.e. 1 ml/16 kg bw at each injection.

The recommended maximum volume to be administered at a single injection site is 10 ml.
50 ml and 100 ml vials can only be broached a maximum of 50 times. 250 ml vials can only be broached a maximum of 85 times

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Cattle:
Subsequent injections must be given at different sites.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.
Before use, shake the bottle vigorously until the product appears adequately resuspended.
The colour of the glass vial may not be uniform making it difficult to determine when the

product is in suspension. Following shaking the absence of sediment can be confirmed most readily by inverting the vial and viewing the contents through the base of the vial.

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 5 days.
Milk: zero hours.

Pigs:
Meat and offal: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
To be supplied only on veterinary prescription.
Do not store above 25ºC
Keep the vial in the outer carton in order to protect from light
Do not use after the expiry date stated on the carton and label after "EXP".Shelf-life after first opening the container: 28 days
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
This product does not contain an antimicrobial preservative.

12. SPECIAL WARNING(S)

Use of "Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle" may constitute a risk to public health due to spread of antimicrobial resistance.
Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle" should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given, may increase the prevalence of resistance. Whenever possible, "Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle" should only be used based on susceptibility testing.

This product selects for resistant strains such as bacteria carrying extended spectrum β-lactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food.

This product is intended for treatment of individual animals. Do not use for disease prevention or as a part of heard health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

Do not use as prophylaxis in case of retained placenta.

Caution should be exercised in animals that have previously shown hypersensitivity reactions to ceftiofur, other cephalosporins, penicillins, or other drugs. If an allergic reaction occurs, no further administrations of ceftiofur should be administered and appropriate therapy for β-lactam hypersensitivity should be instituted.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

The low toxicity of Ceftiofur has been demonstrated in Pigs using Ceftiofur sodium at doses in excess of 8 times the recommended daily dose of Ceftiofur intramuscularly administered for 15 consecutive days.
In cattle, no signs of systemic toxicity have been observed following substantial parenteral overdosages.

Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects or of abortion. Safety of the product has not been investigated in the target species during pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian.

The bactericidal properties of β-lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).

Before use, shake the bottle vigorously until the product appears adequately resuspended. The colour of the glass vial may not be uniform making it difficult to determine when the product is in suspension. Following shaking the absence of sediment can be confirmed most readily by inverting the vial and viewing the contents through the base of the vial.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
50 ml and 100 ml vials can only be broached a maximum of 50 times. 250 ml vials can only be broached a maximum of 85 times

USER WARNINGS
Penicillins and cephalosporins may cause hypersensitivity (allergy) 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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Wash hands after use.

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

Medicines should not be disposed of via wastewater.

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

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

Legal Category:

POM-V

To be supplied only on veterinary prescription.

Package Quantities:
50 ml, 100mL and 250mL type I clear glass vials or high density polyethylene (HDPE) vials.
Each vial is closed with a nitryl bung and sealed with an aluminium cap. 100mL and 250mL type I clear glass vials are presented in a protective plastic sleeve in order to minimise breakage
Not all pack sizes may be marketed

Further Information:
Ceftiofur is a third generation cephalosporin, which is active against many Gram-positive and Gram-negative bacteria. Ceftiofur inhibits the bacterial cell wall synthesis, thereby exerting bactericidal properties. β-lactams act by interfering with synthesis of the bacterial cell wall. Cell wall synthesis is dependent on enzymes that are called penicillin-binding proteins (PBP's). Bacteria develop resistance to cephalosporins by four basic mechanisms: 1) altering or acquiring penicillin binding proteins insensitive to an otherwise effective β -lactam; 2) altering the permeability of the cell to β-lactams; 3) producing β-lactamases that cleave the β -lactam ring of the molecule, or 4) active efflux.

Even though studies in laboratory animals show no evidence of teratogenesis, abortion or influence on reproduction, the reproductive safety of Ceftiofur has not been specifically investigated in pregnant sows or cows. Use only according to a benefit/risk assessment by the responsible veterinarian

FOR ANIMAL TREATMENT ONLY.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle
Cefenil Vet, 50mg/ml Suspension for Injection for Pigs and Cattle [FI]
Ceftiofur (as hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as hydrochloride) 50 mg/ml
A white to yellowish coloured oily suspension.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100ml
250ml

5. TARGET SPECIES

Pigs and Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs:
Single intramuscular injection, for 3 days

Cattle:
Single subcutaneous injection, for 3 to 5 days

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Pigs:
Meat and offal: 5 days.

Cattle:
Meat and offal: 5 days.
Milk: zero hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once broached, /opened, use by: _____

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC
Keep the vial in the outer carton in order to protect from light
This product does not contain an antimicrobial preservative.

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

Disposal: Read package leaflet

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

For animal treatment only

POM-V

To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4330

17. MANUFACTURER'S BATCH NUMBER

BN: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle
Cefenil Vet, 50mg/ml Suspension for Injection for Pigs and Cattle [FI]
Ceftiofur (as hydrochloride)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ceftiofur (as hydrochloride) 50 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER

50 ml

4. ROUTE(S) OF ADMINISTRATION

Pigs:
Single intramuscular injection, for 3 days

Cattle:
Single subcutaneous injection, for 3 to 5 days

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period:
Pigs:
Meat and offal: 5 days.

Cattle:
Meat and offal: 5 days.
Milk: zero hours. .

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening the container: 28 days
Once broached, /opened, use by: _____

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. MARKETING AUTHORISATION NUMBER

Vm 02000/4330

10. OTHER INFORMATION

To be supplied only on veterinary prescription.

PACKAGE LEAFLET
CEFENIL RTU 50 mg/ml, SUSPENSION INJECTION FOR PIGS AND CATTLE
CEFENIL VET, 50MG/ML SUSPENSION FOR INJECTION FOR PIGS AND CATTLE [FI]

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

Marketing authorisation holder and Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle
Cefenil Vet, 50mg/ml Suspension for Injection for Pigs and Cattle [FI]

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

Ceftiofur (as hydrochloride) 50 mg/ml
A white to yellowish coloured oily suspension.

4. INDICATION(S)

Infections associated with bacteria sensitive to ceftiofur:

In Pigs:
For the treatment of bacterial respiratory disease associated with *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Streptococcus suis* sensitive to ceftiofur.

In Cattle:
For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni.*For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with *Fusobacterium necrophorum* and *Porphyromonas asaccharolytica (previously Bacteroides melaninogenicus)*.
For treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Trueperella pyogenes* (previously *Arcanobacterium pyogenes)* and *Fusobacterium necrophorum*. The indication is restricted to cases where treatment with another antimicrobial has failed.

5. CONTRAINDICATIONS

Do not administer to an animal previously found to be hypersensitive to ceftiofur and other β -lactam antibiotics, or to any of the excipient(s).Do not use in cases of known resistance to other cephalosporins or β-lactam antibiotics.

Do not use intravenously.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans

6. ADVERSE REACTIONS

In cattle, mild inflammatory reactions such as hardness at the injection site have been observed in some animals. Clinical resolution is reached in most animals by 21 days after injection.

In pigs, mild reactions at the injection site, such as discolouration of the fascia or fat, have been observed in some animals for up to 20 days after injection.

Hypersensitivity reactions unrelated to dose can occur. Allergic reactions (e.g. skin reactions, anaphylaxis) may occasionally occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon. Alternatively you can report via your national reporting system. For details regarding the national system please contact NCA.

7. TARGET SPECIES

Pigs and Cattle

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

Cattle:
Respiratory disease: 1 mg ceftiofur /kg bw/day for 3 to 5 days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
Acute interdigital necrobacillosis: 1 mg/kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.
Acute post-partum metritis within 10 days after calving: 1 mg/kg bw/day for 5 consecutive days by subcutaneous injection, i.e. 1 ml/50 kg bw at each injection.

Pigs:
3 mg ceftiofur /kg bw/day for 3 days via intramuscular route, i.e. 1 ml/16 kg bw at each injection.

50 ml and 100 ml vials can only be broached a maximum of 50 times. 250 ml vials can only be broached a maximum of 85 times

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing.
The recommended maximum volume to be administered at a single injection site is 10 ml Subsequent injections must be given at different sites.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.
Before use, shake the bottle until the product appears adequately resuspended. The colour of the glass vial may not be uniform making it difficult to determine when the

product is in suspension. Following shaking the absence of sediment can be confirmed most readily by inverting the vial and viewing the contents through the base of the vial.

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 5 days.
Milk: zero hours.

Pigs:
Meat and offal: 5 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep put of the sight and reach of children.
Do not store above 25^{o}C
Keep the vial in the outer carton in order to protect from light
Do not use after the expiry date stated on the carton and label after "EXP".
Shelf-life after first opening the container: 28 days
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
This product does not contain an antimicrobial preservative.

12. SPECIAL WARNING(S)

Use of "Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle" may constitute a risk to public health due to spread of antimicrobial resistance.
Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle" should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly to first line treatment. Official, national and regional antimicrobial policies should be taken into account when the product is used. Increased use, including use of the product deviating from the instructions given, may increase the prevalence of resistance. Whenever possible, "Cefenil RTU, 50 mg/ml, Suspension for Injection for Pigs and Cattle" should only be used based on susceptibility testing.

This product selects for resistant strains such as bacteria carrying extended spectrum β-lactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food.

This product is intended for treatment of individual animals. Do not use for disease prevention or as a part of heard health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

Do not use as prophylaxis in case of retained placenta.

Caution should be exercised in animals that have previously shown hypersensitivity reactions to ceftiofur, other cephalosporins, penicillins, or other drugs. If an allergic

reaction occurs, no further administrations of ceftiofur should be administered and appropriate therapy for β-lactam hypersensitivity should be instituted.

The low toxicity of ceftiofur has been demonstrated in Pigs using ceftiofur sodium at doses in excess of 8 times the recommended daily dose of ceftiofur intramuscularly administered for 15 consecutive days.
In cattle, no signs of systemic toxicity have been observed following substantial parenteral overdosages.

Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects or of abortion. Safety of the product has not been investigated in the target species during pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian.

The bactericidal properties of β-lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).

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

Before use, shake the bottle vigorously until the product appears adequately resuspended. The colour of the glass vial may not be uniform making it difficult to determine when the product is in suspension. Following shaking the absence of sediment can be confirmed most readily by inverting the vial and viewing the contents through the base of the vial.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
50 ml and 100 ml vials can only be broached a maximum of 50 times. 250 ml vials can only be broached a maximum of 85 times

USER WARNINGS

Penicillins and cephalosporins may cause hypersensitivity (allergy) 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.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, taking all recommended precautions.
3. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

Wash hands after use.

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

April 2019

15. OTHER INFORMATION

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

Legal Category:

POM-V

To be supplied only on veterinary prescription.

Package Quantities:
50 ml, 100mL and 250mL type I clear glass vials or high density polyethylene (HDPE) vials.
Each vial is closed with a nitryl bung and sealed with an aluminium cap. 100mL and 250mL type I clear glass vials are presented in a protective plastic sleeve in order to minimise breakage
Not all pack sizes may be marketed

Further Information:
ceftiofur is a third generation cephalosporin, which is active against many Gram-positive and Gram-negative bacteria. ceftiofur inhibits the bacterial cell wall synthesis, thereby exerting bactericidal properties. β-lactams act by interfering with synthesis of the bacterial cell wall. Cell wall synthesis is dependent on enzymes that are called penicillin-binding proteins (PBP's). Bacteria develop resistance to cephalosporins by four basic mechanisms: 1) altering or acquiring penicillin binding proteins insensitive to an otherwise effective β -lactam; 2) altering the permeability of the cell to β-lactams; 3) producing β-lactamases that cleave the β -lactam ring of the molecule, or 4) active efflux.

Even though studies in laboratory animals show no evidence of teratogenesis, abortion or influence on reproduction, the reproductive safety of ceftiofur has not been specifically investigated in pregnant sows or cows. Use only according to a benefit/risk assessment by the responsible veterinarian

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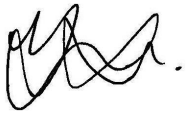
FOR ANIMAL TREATMENT ONLY.



Approved: 09 August 2019