LABEL

CEFENIL STERILE POWER 1 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50mg/ml Powder and Solvent for Solution for Injection for Cattle and Pigs.
Ceftiofur (as ceftiofur sodium).

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each vial contains ceftiofur sodium equivalent to 1 g ceftiofur to be reconstituted with 20 ml of water for injection.
Reconstituted solution contains 50 mg ceftiofur per ml.

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

1 g (30ml vial).

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle and pigs.

5. WITHDRAWAL PERIOD

Cattle Meat and offal: 2 days.
Milk: zero hours.
Pigs Meat and offal: 2 days.

6. BATCH NUMBER

BN:

DOM:

7. EXPIRY DATE

Exp:

Once broached/opened, use by …….

Shelf-life of the veterinary medicinal product after reconstitution:
24 hours stored in a refrigerator (2°C to 8ºC).

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

POM-V

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for user warnings.

ManA 2000

LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Water for Reconstitution of Cefenil 50 mg/ml Powder for Solution for Injection for Cattle and Pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

The product contains 100% v/v Water for Injections

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

20ml

4. METHOD AND ROUTE(S) OF ADMINISTRATION

Solvent for reconstitution of Cefenil 50mg/ml Sterile Powder and Solvent for Solution for Injection for Cattle and Pigs.
Intramuscular use in cattle and pigs.

Read the Cefenil package leaflet before use.

5. WITHDRAWAL PERIOD

Not applicable for the solvent.
Read the Cefenil package leaflet before use.

6. BATCH NUMBER

BN:

DOM:

7. EXPIRY DATE

Exp:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

POM-V

ManA: 2000

LABEL

CEFENIL STERILE POWER 4 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50mg/ml Powder and Solvent for Solution for Injection for Cattle and Pigs.
Ceftiofur (as ceftiofur sodium).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each vial contains ceftiofur sodium equivalent to 4 g ceftiofur to be reconstituted with 80 ml of water for injection.
Reconstituted solution contains 50 mg ceftiofur per ml.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. PACKAGE SIZE

4 g (100ml vial).

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle and pigs.

8. WITHDRAWAL PERIOD

Cattle Meat and offal: 2 days.
Milk: zero hours.
Pigs Meat and offal: 2 days.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindicated in animals previously found to be hypersensitive to ceftiofur.

Operator Warnings:
Penicillins/cephalosporins may occasionally cause severe allergic reactions. See Package Insert for full user and other warnings/precautions.

10. EXPIRY DATE

Exp:

Once broached/opened, use by …….

Shelf-life of the veterinary medicinal product after reconstitution:
24 hours stored in a refrigerator **(**2°C to 8ºC).

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light. Store unreconstituted product and diluent in a refrigerator (2°C to 8°C).

After reconstitution, the product may be stored in a refrigerator (2°C to 8°C) for no longer than 24 hours.

Any reconstituted product remaining after the stated periods should be discarded.

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

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Newry
Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4278

17. MANUFACTURER'S BATCH NUMBER

BN:

DOM:

LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Water for Reconstitution of Cefenil 50 mg/ml Powder for Solution for Injection for Cattle and Pigs.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

The product contains 100% v/v Water for Injections

3. PHARMACEUTICAL FORM

Solvent for parenteral use.

4. PACKAGE SIZE

80ml

5. TARGET SPECIES

Cattle and pigs

6. INDICATION(S)

Water for Injections is intended for use as a sterile solvent for the reconstitution of Cefenil Sterile Powder for parenteral administration.

Refer to Cefenil package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Solvent for reconstitution of Cefenil 50mg/ml Sterile Powder and Solvent for Solution for Injection for Cattle and Pigs.
Intramuscular use in cattle and pigs.

Read the Cefenil package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable for the solvent.
Read the Cefenil package leaflet before use.

9. SPECIAL WARNING(S), IF NECESSARY

Refer to Cefenil package leaflet.

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C to 8°C). Keep container in the outer carton in order to protect from light.

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

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4278

17. MANUFACTURER'S BATCH NUMBER

BN:

CARTON

CEFENIL STERILE POWDER 1 G

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50mg/ml Powder and Solvent for Solution for Injection for Cattle and Pigs.
Ceftiofur (as ceftiofur sodium).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each powder vial contains 1 g ceftiofur as ceftiofur sodium.

Each diluent vial contains 20ml Water for Injections.

Reconstituted solution contains 50 mg ceftiofur per ml.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. PACKAGE SIZE

1 g powder vial [30 ml].
20 ml diluent vial [30ml].

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

For the treatment of bacterial respiratory disease in cattle and pigs. For the treatment of foul in the foot of cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle and pigs.

Reconstitution
1 g vial : Reconstitute by adding 20 ml water for injection.

For ease of reconstitution use an 18 G needle. Rapid addition of diluent will give best results.

Dosage in cattle and pigs.

Target Species	Dosage	Dosage of reconstituted product	Indication	Frequency of administration
Cattle	1 mg/kg	1ml/50kg	Respiratory disease	Once daily at 24 hour intervals for 3-5 days in total
			Foul in the foot	Once daily at 24 hour intervals for 3 days in total
Pigs	3 mg/kg	1ml/16kg	Respiratory disease	Once daily at 24 hour intervals for 3 days in total

Do not administer more than 10 ml per injection site.

Administration
The intramuscular route only should be used in cattle and pigs. In the pig, particular care must be taken to avoid injection into fat tissue.

Normal aseptic injection techniques should be practised.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle Meat and offal: 2 days.
Milk: zero hours.
Pigs Meat and offal: 2 days.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warning: Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user and other warnings/precautions.

10. EXPIRY DATE

Exp:

Once broached/opened, use by …….

Shelf-life of the veterinary medicinal product after reconstitution:
24 hours stored in a refrigerator (2°C to 8ºC).

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

Store unreconstituted product and diluent in a refrigerator (2°C to 8°C).

After reconstitution, the product may be stored in a refrigerator (2°C to 8°C) for no longer than 24 hours.

Any reconstituted product remaining after the stated periods should be discarded.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

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.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Newry, Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4278

MARKETING AUTHORISATION NUMBER

POM-V

17. MANUFACTURER'S BATCH NUMBER

BN:

LOGO

CARTON

CEFENIL STERILE POWDER 4 G

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50mg/ml Powder and Solvent for Solution for Injection for Cattle and Pigs.
Ceftiofur (as ceftiofur sodium).

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each powder vial contains 4 g ceftiofur as ceftiofur sodium.

Each diluent vial contains 80ml Water for Injections.

Reconstituted solution contains 50 mg ceftiofur per ml.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. PACKAGE SIZE

4 g powder vial [100 ml].
80 ml diluent vial [100ml].

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

For the treatment of bacterial respiratory disease in cattle and pigs. For the treatment of foul in the foot of cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle and pigs.

Reconstitution
4 g vial : Reconstitute by adding 80 ml water for injection.

For ease of reconstitution use an 18 G needle. Rapid addition of diluent will give best results.

Dosage in cattle and pigs.

Target Species	Dosage	Dosage of reconstituted product	Indication	Frequency of administration
Cattle	1 mg/kg	1ml/50kg	Respiratory disease	Once daily at 24 hour intervals for 3-5 days in total
			Foul in the foot	Once daily at 24 hour intervals for 3 days in total
Pigs	3 mg/kg	1ml/16kg	Respiratory disease	Once daily at 24 hour intervals for 3 days in total

Do not administer more than 10 ml per injection site.

Administration
The intramuscular route only should be used in cattle and pigs. In the pig, particular care must be taken to avoid injection into fat tissue.

Normal aseptic injection techniques should be practised.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle Meat and offal: 2 days.
Milk: zero hours.
Pigs Meat and offal: 2 days.

9. SPECIAL WARNING(S), IF NECESSARY

Operator warning: Penicillins/cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user and other warnings/precautions.

10. EXPIRY DATE

Exp:

Once broached/opened, use by …….

Shelf-life of the veterinary medicinal product after reconstitution:
24 hours stored in a refrigerator (2°C to 8ºC).

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton in order to protect from light.

Store unreconstituted product and diluent in a refrigerator (2°C to 8°C).

After reconstitution, the product may be stored in a refrigerator (2°C to8°C) for no longer than 24 hours.

Any reconstituted product remaining after the stated periods should be discarded.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

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.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Newry, Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4278

MARKETING AUTHORISATION NUMBER

POM-V

17. MANUFACTURER'S BATCH NUMBER

BN:

LOGO

PACKAGE LEAFLET

CEFENIL 50MG/ML POWDER AND SOLVENT FOR SOLUTION FOR INJECTION FOR CATTLE AND PIGS.
(Ceftiofur Sodium)

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

Marketing authorisation holder:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Limited
Newry, Co Down
Northern Ireland

Manufacturer Responsible for Batch Release:
Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Newry, Co Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50mg/ml Powder and Solvent for Solution for Injection for Cattle and Pigs.
Ceftiofur (as ceftiofur sodium).

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

The product is an off white to tan coloured free flowing powder packaged in vials which contain ceftiofur sodium equivalent to 1 g or 4 g ceftiofur.

Each diluent vial contains 20ml or 80ml Water for Injections.

Reconstituted solution contains 50 mg ceftiofur per ml.

4. INDICATION(S)

The product contains ceftiofur which is a beta-lactamase resistant, broad spectrum bactericidal cephalosporin antibiotic. The product is indicated for:

1) the treatment of cattle with acute respiratory disease in which *Mannheima haemolytica, Pasteurella multocida or Histophilus somni* sensitive to ceftiofur are involved.

2) the treatment of cattle with acute interdigital necrobacillosis (foul in the foot) in which *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* are involved.

3) the treatment of pigs with bacterial respiratory disease in which *Actinobacillus pleuropneumoniae, Pasteurella multocida* and/or *Streptococcus suis* sensitive to ceftiofur are involved.

5. CONTRAINDICATIONS

The use of the product is contraindicated in animals previously found to be hypersensitive to ceftiofur and other beta-lactam antibiotics.
Do not use in case of known resistance to the active substance.
Do not use in cases where resistance to other cephalosporins or beta-lactam antibiotics has occurred.
The use of this product may cause transient local discomfort at the site of injection.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. ADVERSE REACTIONS

Hypersensitivity reactions can occasionally occur. In the case of an allergic reaction, treatment should be stopped.
In pigs, local irritation at the injection site may occur and can persist for 5 days or more.

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

7. TARGET SPECIES

Cattle and pigs.

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

Reconstitution
1 g vial : Reconstitute by adding 20 ml water for injection.
4 g vial : Reconstitute by adding 80 ml water for injection.

Directions for Reconstitution:
1. Remove stopper overseal from diluent and sterile powder vials.
2. Remove exactly the required volume of Water for Injections using a sterile 18G needle and syringe.
3. Inject the exact volume of diluent into sterile powder vial.
4. Shake solution until complete reconstitution of powder occurs.
Rapid addition of diluent maintained at room temperature will give best results. Normally accepted aseptic technique should be followed during reconstitution to avoid microbial contamination.

Dosage in cattle and pigs.

Target Species	Dosage	Dosage of reconstituted product	Indication	Frequency of administration
Cattle	1 mg/kg	1ml/50kg	Respiratory disease	Once daily at 24 hour intervals for 3-5 days in total
			Foul in the foot	Once daily at 24 hour intervals for 3 days in total
Pigs	3 mg/kg	1ml/16kg	Respiratory disease	Once daily at 24 hour intervals for 3 days in total

Do not administer more than 10 ml per injection site.

9. ADVICE ON CORRECT ADMINISTRATION

The intramuscular route only should be used in cattle and pigs. In the pig, particular care must be taken to avoid injection into fat tissue.

Normal aseptic injection techniques should be practised.

The product is recommended for a single administration only. Avoid repeated injection at the same site.

In pigs, an appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting piglets weighing less than 16kg.

10. WITHDRAWAL PERIOD

Cattle Meat and offal: 2 days.
Milk: zero hours.
Pigs Meat and offal: 2 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton in order to protect from light.

Store unreconstituted product in a refrigerator (2°C to 8°C).

After reconstitution, the product may be stored in a refrigerator (2°C to 8°C) for up to 24 hours.

Any reconstituted product remaining after the stated periods should be discarded.

Keep out of the sight and reach of children.

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

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. The discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

User Safety Warnings:

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-sensitivity 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 sensitized, 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 and eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Special Precautions for Use in Animals:

Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to ceftiofur and may decrease the effectiveness of treatment with other cephalosporins, due to the potential for cross resistance.

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

In the pig, particular care must be taken to avoid injection into the fat tissue.

Avoid repeated injection at the same site.

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

Use during pregnancy, lactation or lay

Laboratory studies in the rat have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.
The safety of the veterinary medicinal product has not been assessed during pregnancy and lactation in cattle or pigs. Use only according to the benefit/risk assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes)

In cattle, no evidence of systemic toxicity was observed following administration of an overdose.
In pigs, no evidence of systemic toxicity was observed following administration doses of up to 8 times the recommended dose, administered daily by intramuscular injection for 15 days.

Incompatibilities

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

Use of Cefenil 50mg/ml Powder and Solvent for Solution for Injection may constitute a risk to public health due to spread of antimicrobial resistance.

The product 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, the product should only be used based on susceptibility testing.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

15. OTHER INFORMATION

MARKETING AUTHORISATION NUMBER

POM-V

Package Quantities:
One vial with 1 g Cefenil Sterile Powder with one vial with 20 ml Water for Injections per carton in packs of 1, 6 and 12 presentations.
One vial with 4 g Cefenil Sterile Powder with one vial with 80 ml Water for Injections per carton in packs of 1, 6 and 12 presentations.

Not all pack sizes may be marketed.

Further Information:
After recommended dose, therapeutic levels of ceftiofur are achieved within a few minutes and are maintained for at least 24 hours.

ManA 2000

FOR ANIMAL TREATMENT ONLY.

LOGO

Approved: 04 December 2019