DRAFT LABEL

CEFENIL STERILE POWER 1 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50 mg/ml Powder and Solvent for Solution for Injection for Cattle, Pigs and Horses.
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

4. ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle, pigs and horses.

5. WITHDRAWAL PERIOD

Cattle Meat and offal: 1 day.
Milk: zero hours.
Pigs Meat and offal: 2 days.

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

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 (2-8ºC).

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.

Vm 02000/4306

ManA 2000

DRAFT LABEL

CEFENIL STERILE POWER 4 g

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50 mg/ml Powder and Solvent for Solution for Injection for Cattle, Pigs and Horses.
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 (100 ml vial)

5. TARGET SPECIES

Cattle, pigs, and horses.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle, pigs, and horses.

8. WITHDRAWAL PERIOD

Cattle Meat and offal: 1 day.
Milk: zero hours.
Pigs Meat and offal: 2 days.

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

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 - 8 ºC).

11. SPECIAL STORAGE CONDITIONS

Store unreconstituted product and diluent in a refrigerator (2-8°C).
Keep the container in the outer carton in order to protect from light.
After reconstitution, the product may be stored in a refrigerator (2-8°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

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.

POM-V

Prescription Only Medicine

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

Manufacturer:
Norbrook Laboratories Limited
Newry
Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4306

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

BN:

DOM:

DRAFT CARTON
CEFENIL STERILE POWDER 1 G

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50 mg/ml Powder and Solvent for Solution for Injection for Cattle, Pigs and Horses.
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 20 ml 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 [30 ml].

5. TARGET SPECIES

Cattle, pigs, and horses.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle, pigs and horses.

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, pigs and horses.

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
Horses	2 mg/kg	2ml/50kg	Respiratory disease	Once daily at 24 hour intervals for up to 10 days in total (or 48 hours after clinical signs have disappeared)

Do not administer more than 10 ml per injection site.

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

Normal aseptic injection techniques should be practised.

8. WITHDRAWAL PERIOD

Cattle Meat and offal: 1 day.
Milk: zero hours.
Pigs Meat and offal: 2 days.

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

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 **(**2-8ºC).

11. SPECIAL STORAGE CONDITIONS

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

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

After reconstitution, the product may be stored in a refrigerator (2-8°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

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.

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

Marketing Authorisation Holder:
Norbrook Laboratories Limited
Newry, Co Down
Northern Ireland.

16. MARKETING AUTHORISATION NUMBER

ManA 2000

MARKETING AUTHORISATION NUMBER
Vm 02000/4306

POM-V **Prescription Only Medicine**

Distributed in the UK by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

17. MANUFACTURER'S BATCH NUMBER

BN:

LOGO

DRAFT CARTON

CEFENIL STERILE POWDER 4 G

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cefenil 50 mg/ml Powder and Solvent for Solution for Injection for Cattle, Pigs and Horses.
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 80 ml 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 [100 ml].

5. TARGET SPECIES

Cattle, pigs, and horses.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use in cattle, pigs, and horses.

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, pigs and horses.

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
Horses	2 mg/kg	2ml/50kg	Respiratory disease	Once daily at 24 hour intervals for up to 10 days in total (or 48 hours after clinical signs have disappeared)

Do not administer more than 10 ml per injection site.

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

Normal aseptic injection techniques should be practised.

8. WITHDRAWAL PERIOD

Cattle Meat and offal: 1 day.
Milk: zero hours.
Pigs Meat and offal: 2 days.

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

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 **(**2-8 ºC).

11. SPECIAL STORAGE CONDITIONS

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

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

After reconstitution, the product may be stored in a refrigerator (2-8°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

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.

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

Marketing Authorisation Holder:
Norbrook Laboratories Limited
Newry, Co Down
Northern Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000

MARKETING AUTHORISATION NUMBER
Vm 02000/4306

POM-V **Prescription Only Medicine**

Distributed in the UK by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

17. MANUFACTURER'S BATCH NUMBER

BN:

LOGO

LEAFLET

CEFENIL STERILE POWDER
(Ceftiofur Sodium)

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

Norbrook Laboratories Limited
Newry, Co Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Powder vial contains:

Active Substance	
Ceftiofur (as ceftiofur sodium)	1 g
Or	
Ceftiofur (as ceftiofur sodium)	4 g

Solvent contains: Water for Injection

One ml of reconstituted solution contains:

Active Substance	
Ceftiofur (as ceftiofur sodium)	50 mg

Powder: off white to brown coloured powder
Solvent: clear, colourless, solution
Reconstituted solution: clear solution, free of particulates

4. INDICATION(S)

The product is indicated for treatment of infections associated with bacteria sensitive to ceftiofur as follows:

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

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

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

4) treatment of horses with bacterial respiratory disease in which *Streptococcus* spp (including *Streptococcus zooepidemicus* and *Streptococcus equi*), *Staphylococcus* spp and/or *Pasteurella* spp are involved.

5. CONTRAINDICATIONS

Do not use in known cases of hypersensitivity to the active substance, to other beta-lactam antibiotics or to any of the excipients.

Do not use in known cases of resistance to the active substance, other cephalosporins or beta-lactam antibiotics.

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

6. ADVERSE REACTIONS

The use of this product may cause transient local discomfort at the site of injection. 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs, and horses.

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

This product is for intramuscular use only.

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.

The resulting solution contains 50 mg ceftiofur per ml.

Dosage in cattle, pigs and horses.

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
Horses	2 mg/kg	2ml/50kg	Respiratory disease	Once daily at 24 hour intervals for up to 10 days in total (or 48 hours after clinical signs have disappeared)

Do not administer more than 10 ml per injection site.

9. ADVICE ON CORRECT ADMINISTRATION

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.

Do not exceed 20 broachings per vial. If more than 20 broachings are required, the use of a draw-off needle is recommended.

10. WITHDRAWAL PERIOD

Cattle Meat and offal: 1 day.
Milk: zero hours.
Pigs Meat and offal: 2 days.
Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

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

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

After reconstitution, the product may be stored in a refrigerator (2-8°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 after the expiry date stated on the label and carton.

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

Special warnings for each target species:

The administration of antimicrobials to horses under conditions of stress may be associated with acute diarrhoea, which could be fatal. If acute diarrhoea is observed, discontinue use of this antimicrobial and initiate appropriate therapy.

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:

Ceftiofur should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to more narrow spectrum antimicrobials.
Official and national antimicrobial policies should be taken into account when the product is used.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
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.

This product selects for resistant strains such as bacteria carrying extended spectrum beta-lactamases (ESB) 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 sue 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.

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

Avoid repeated injection at the same site.

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, pigs or horses. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction

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

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.

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.
Cefenil 50mg/ml Powder and Solvent for Solution for Injection 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 50mg/ml Powder and Solvent for Solution for Injection should only be used based on susceptibility testing.

Incompatibilities

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

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

MARKETING AUTHORISATION NUMBER
Vm 02000/4306

POM-V

Prescription Only Medicine

Distributed in the UK by:
Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

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

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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, Pigs and Horses.
Intramuscular use in cattle, pigs and horses.

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

Vm 02000/4306

ManA: 2000

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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, pigs and horses.

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, Pigs and Horses.
Intramuscular use in cattle, pigs and horses.

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 (2-8°C).
Keep container in outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

POM-V

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
Newry
Co. Down, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 02000/4306

ManA: 2000

17. MANUFACTURER'S BATCH NUMBER

BN:

Approved: 26 September 2017

D Austin