PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>
BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftiocyl 50 mg/ml, suspension for injection for cattle and pigs
Ceftiofur

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as hydrochloride) 50.0 mg /ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

Vial of 50 ml
Vial of 100 ml
Vial of 250 ml

5. TARGET SPECIES

Already mentioned in the name.

6. INDICATION(S)

Not included

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: Intramuscular route 1 ml/16kg/day
Cattle: Subcutaneous route 1 ml/50kg/day
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 6 days.
Cattle:
Meat and offal: 8 days.
Milk: zero hour.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first broaching the vial: 28 days.
Once broached, use by

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4122

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>
Label of 100 and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftiocyl 50 mg/ml, suspension for injection for cattle and pigs
Ceftiofur

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as hydrochloride) 50.0 mg /ml

3. PHARMACEUTICAL FORM

Not requested

4. PACKAGE SIZE

Vial of 100 ml
Vial of 250 ml

5. TARGET SPECIES

Already mentioned in the name.

6. INDICATION(S)

Not included

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pigs: Intramuscular route : 1 ml/16kg/day
Cattle: Subcutaneous route: 1 ml/50kg/day
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 6 days.
Cattle:
Meat and offal: 8 days.
Milk: zero hour.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first broaching the vial: 28 days.
Once broached, use by

11. SPECIAL STORAGE CONDITIONS

Not applicable.

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"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4122

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Label of 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftiocyl 50 mg/ml, suspension for injection for cattle and pigs
Ceftiofur

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as hydrochloride) 50.0 mg /ml

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

Vial of 50 ml.

4. ROUTE OF ADMINISTRATION

Pigs: Intramuscular route: 1 ml/16kg/day
Cattle: Subcutaneous route: 1 ml/50kg/day

5. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 6 days.
Cattle:
Meat and offal: 8 days.
Milk: zero hour.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Shelf-life after first broaching the vial: 28 days.
Once broached, use by

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Ceftiocyl 50 mg/ml, suspension for injection for cattle and pigs

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>:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release:
VETOQUINOL
MAGNY-VERNOIS
F-70200 LURE
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ceftiocyl 50 mg/ml, suspension for injection for cattle and pigs
Ceftiofur

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

Each ml contains:
Active substance: Ceftiofur (as hydrochloride) 50.0 mg/ml

Slightly yellow to slightly pink, milky 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 *Pasteurella haemolytica* (*Mannheimia* spp.), *Pasteurella multocida* and *Haemophilus somnus*.
For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* (*Porphyromonas asaccharolytica*).

For treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Escherichia coli*, *Arcanobacterium pyogenes* and *Fusobacterium necrophorum*, sensitive to ceftiofur. 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.
Do not use in case of known resistance to the active substance.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to human.

6. ADVERSE REACTIONS

Hypersensitivity reactions unrelated to dose can occur. Allergic reactions (e.g. skin reactions, anaphylaxia) may occasionally occur.
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.
In cattle, mild inflammatory reactions at the injection site, such as tissue oedema and discoloration of the subcutaneous tissue and/or fascial surface of the muscle may be observed. Clinical resolution is reached in most animals by 10 days after injection although slight tissue discoloration may persist for 28 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

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

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.

Subsequent injections must be given at different sites. For the injections, the neck should be preferred in cattle.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Pigs:
Meat and offal: 6 days.
Cattle:
Meat and offal: 8 days.
Milk: zero hour.

11. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special storage conditions.
Keep out of the sight and reach of children.
Shelf-life after first broaching the vial: 28 days.
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. This discard date should be written in the space provided on the label.
Do not use after the expiry date stated on the carton and vial after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Accidental injection is dangerous.

Special precautions for use in animals:
Shake the bottle well before use to bring the product back into suspension.
In case of the occurrence of allergic reaction the treatment should be withdrawn.

Use of Ceftiocyl may constitute a risk to public health due to spread of antimicrobial resistance.
Ceftiocyl 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, Ceftiocyl should only be used based on susceptibility testing.
Ceftiocyl 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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. In case of accidental injection or 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 in breathing are more serious symptoms and require urgent medical attention.

Wash hands after use.

Use during pregnancy, lactation or lay
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.

Interaction with other medicinal products and other forms of interaction:
Erythromycins and tetracyclines may have an antagonistic effect on cephalosporins whereas aminoglycosides may have a potentiating effect.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

<Medicines should not be disposed of via wastewater or household waste.>
<Ask your <veterinary surgeon><pharmacist> how to dispose of medicines no longer required. These measures should help to protect the environment.>

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Presentation

50,100 and 250 ml dark type I vial closed with a bromobutyl rubber stopper and aluminium cap.
Cardboard box with 1 glass vial of 50 ml:
Cardboard box with 1 glass vial of 100 ml:
Cardboard box with 1 glass vial of 250 ml:
Not all pack sizes may be marketed.

Approved: 11 September 2018