# ANNEX III
# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON BOX**
50/100 /250 ml glass vial

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFTIOCYL Fluid 50 mg/ml, suspension for injection for pigs and cattle

Ceftiofur (as hydrochloride)

## 2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride)..... 50.0 mg/ml

## 3. PHARMACEUTICAL FORM

Suspension for injection

## 4. PACKAGE SIZE

50 ml
100ml 250ml

## 5. TARGET SPECIES

Cattle, pigs

## 6. INDICATION(S)

Not required

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular (pigs) or subcutaneous (cattle) route.
Shake well before use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

Pigs: meat and offal: 2 days.
Cattle: meat and offal: 6 days; milk: zero hours.

## 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 opening the immediate packaging: 28 days. Once broached, use by: ...

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store the vial upright.

## 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 08007/4146

## 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE** Label of 100 and 250 ml vials

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEFTIOCYL Fluid 50 mg/ml, suspension for injection for pigs and cattle
Ceftiofur (as hydrochloride)

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as hydrochloride) ..... 50.0 mg/ml

## 3. PHARMACEUTICAL FORM

Not requested

## 4. PACKAGE SIZE

100 ml
250 ml

## 5. TARGET SPECIES

Cattle, pigs

## 6. INDICATION(S)

Not included

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular (pigs) or subcutaneous cattle) route.
Shake well before use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Pigs: meat and offal: 2 days.
Cattle: meat and offal: 6 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 immediate packaging: 28 days.

Once broached, use by:

## 11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store the vial upright.

## 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 08007/4146

## 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 Fluid 50 mg/ml, suspension for injection for pigs and cattle
Ceftiofur (as hydrochloride)

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ceftiofur (as hydrochloride) ..... 50.0 mg/ml

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

50 ml

## 4. ROUTE(S) OF ADMINISTRATION

IM (pigs) or SC (cattle)
Read the package leaflet before use.

## 5. WITHDRAWAL PERIOD(S)

Pigs: meat and offal: 2 days.
Cattle: meat and offal: 6 days; milk: zero hours.

## 6. BATCH NUMBER

Batch {number}

## 7. EXPIRY DATE

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

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET:

CEFTIOCYL Flow suspension, 50 mg/ml, suspension for injection for pigs and 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 <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 SA
MAGNY-VERNOIS
F-70200 LURE
FRANCE

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

| Name | Countries |
|---|---|
| CEFTIOCYL Flow 50 mg/ml, suspension for injection for pigs and cattle | Austria, Belgium, Bulgaria, Cyprus, Croatia, Czech Republic, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Romania, Slovakia, Slovenia |
| CEFTIOCYL Fluid 50 mg/ml, suspension for injection for pigs and cattle | United Kingdom, Ireland |
| CEFTIOCYL Evo 50 mg/ml, suspension for injection for pigs and cattle | Spain, Portugal |
| CEFTIOCYL Vet 50 mg/ml, suspension for injection for pigs and cattle | Finland, Norway, Sweden |

Ceftiofur (as hydrochloride)

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

One ml contains:
Active substance(s):
Ceftiofur (as hydrochloride) ..... 50.0 mg
Slightly yellow to slightly pink, milky suspension.

## 4. INDICATION(S)

Infections associated with bacteria sensitive to the antibiotic 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 foot rot (acute interdigital necrobacillosis, panaritium), associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus.* For treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Escherichia coli, Trueperella pyogenes* (former *Arcanobacterium pyogenes*) and *Fusobacterium necrophorum*, sensitive to ceftiofur, where treatment with another antimicrobial has failed.

## 5. CONTRAINDICATIONS

Do not inject intravenously.
Do not use in poultry (including eggs) due to the risk of spread of antimicrobial resistance to humans. Do not use in cases of hypersensitivity to ceftiofur, to any other β-lactam antibiotics, or to any of the excipients.
Do not use in cases of known resistance to ceftiofur or other β-lactam antibiotics.

## 6. ADVERSE REACTIONS

Hypersensitivity reactions unrelated to dose can occur. Allergic reactions (e.g. skin reactions, anaphylaxis) 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 to moderate inflammatory reactions were observed following SC injection, presenting as firmness and swelling at the injection site. Chronic inflammation at these sites observed in most animals until 42 days post-injection.
Discoloration of the subcutaneous tissue and/or fascial surface of the muscle at the injection site may be observed. Slight tissue discoloration may persist for 28 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

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

For intramuscular (pigs) or subcutaneous (cattle) route.
Pigs:
3 mg ceftiofur /kg bw/day for 3 days via intramuscular route, i.e. 1 ml/16 kg bw at each injection. Not more than 4 ml should be administered per injection site.
Subsequent injections must be given at different sites.

Cattle:
Respiratory disease: 1 mg ceftiofur /kg bw/day for 3 to 5 days by subcutaneous injection, i.e. 1 ml/50kg bw at each injection.
Acute interdigital necrobacillosis: 1 mg/kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml/50kg 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.
Not more than 13 ml should be administered per injection site.
Subsequent injections must be given at different sites.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

Before use, shake the bottle vigorously for a maximum of 60 seconds or until the product appears adequately resuspended.
The closures must not be broached more than 30 times. Otherwise, the use of a multiple-dose syringe is recommended.

## 10. WITHDRAWAL PERIOD(S)

Pigs: meat and offal: 2 days.
Cattle: meat and offal: 6 days; milk: zero hours.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C. Store the vial upright.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after “EXP”. The expiry date refers to the last day of that month.
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 carton should be discarded should be worked out. This discard date should be written in the space provided.

## 12. SPECIAL WARNING(S)

Special precautions for use in animals:
In case of the occurrence of allergic reaction the treatment should be withdrawn.
The product selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) which may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, this product should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis), to more narrow spectrum antimicrobial 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 in the SPC, may increase the prevalence of ceftiofur/beta lactam resistant bacteria. Whenever possible, this product should only be used based on susceptibility testing.
Do not use as prophylaxis in case of retained placenta.
The product is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programs. Treatment of groups of animals should be strictly limited to ongoing disease outbreaks according to the approved conditions of use.

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.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
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.
Avoid contact with eyes and skin. In case of contact, wash immediately with plenty water.
Use during pregnancy, lactation or lay:
The safety of the product has not been established in sows or cows during pregnancy or lactation. Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Use only according to a benefit/risk assessment by the responsible veterinarian.
Interaction with other medicinal products and other forms of interaction:
The bactericidal properties of cephalosporins are antagonized by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).
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

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

## 15. OTHER INFORMATION

Dark brown transparent type I glass vial with grey bromobutyl rubber stopper and sealed with aluminium cap, with flip-off.

Pack sizes:

Box with 1 vial of 50 ml Box with 1 vial of 100 ml Box with 1 vial of 250 ml

Not all pack sizes may be marketed.

Approved: 11 September 2018