ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride) 50 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: subcutaneous use
Pigs: intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Pigs:
Meat and offal: 5 days

Cattle:
Meat and offal: 8 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:
Shelf life after first opening the container: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Keep the vial in the outer carton in order to protect from light.

12. SPECIFIC 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 product 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.
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

Kela – Kempisch Laboratorium – Kela Laboratoria NV, St Lenaartseweg 48, 2320 Hoogstraten, BELGIUM

16. MARKETING AUTHORISATION NUMBER

Vm 06126/4007

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as hydrochloride) 50 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Pigs and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: subcutaneous use
Pigs: intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Pigs:
Meat and offal: 5 days

Cattle:
Meat and offal: 8 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:
Shelf life after first opening the container: 28 days.

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Keep the vial in the outer carton in order to protect from light.

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

Kela – Kempisch Laboratorium – Kela Laboratoria NV, St Lenaartseweg 48, 2320 Hoogstraten, BELGIUM

16. MARKETING AUTHORISATION NUMBER

Vm 06126/4007

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Cefokel 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:
Kela – Kempisch Laboratorium – Kela Laboratoria NV
St. Lenaartseweg 48
2320 Hoogstraten
Belgium

Manufacturer responsible for batch release:
KELA N.V.
St. Lenaartseweg 48
2320 Hoogstraten
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

One ml of suspension contains:

Ceftiofur (as hydrochloride) 50,0 mg

White to off-white, beige suspension

4. INDICATIONS

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* (previously *Pasteurella haemolytica*), *Pasteurella multocida* and *Histophilus somni* (previously *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 use in cases of hypersensitivity to ceftiofur and other β-lactam antibiotics. Do not inject intravenously.
Do not use in cases where resistance to other cephalosporins or beta-lactam antibiotics has occurred.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. ADVERSE REACTIONS

Hypersensitivity reactions unrelated to dose can occur. Allergic reactions (e.g. skin reactions, anaphylaxia) may occasionally occur. In case of the occurrence of allergic reaction the treatment should be withdrawn.

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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Pigs and cattle

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.

Before use, shake the bottle vigorously for at least 30 seconds until the product appears adequately resuspended. Following shaking the bottle should be visually examined to ensure that the product is brought back into suspension. The absence of settled material can be confirmed by inverting the vial and viewing the contents through the base of the vial.

The recommended maximum volume to be administered at a single injection site is 4 ml in pigs and 6 ml in cattle. Subsequent injections must be given at different sites. Subsequent injections must be given at different sites.
The vial cannot be broached more than 66 times.

In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Pigs:
Meat and offal: 5 days

Cattle:
Meat and offal: 8 days
Milk: zero hours

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not refrigerate or freeze.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
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 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.

12. SPECIAL WARNING(S)

Use of the product 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.

Special warnings for each target species:

None.

Special precautions for use in animals:

This veterinary medicinal product does not contain any antimicrobial preservative.

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 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.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
Handle this product with great care to avoid exposure. Wash hands after use.
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.

Pregnancy and lactation:
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:
The bactericidal properties of Beta-lactams are neutralised 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

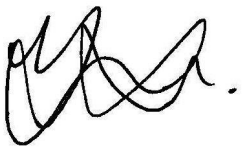
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

Vials of 100 ml.
Vials are individually packed in a carton box.
One, six, ten or twelve vials are grouped as a clinical pack.
Not all pack sizes may be marketed.



Approved: 12 October 2022