PARTICULARS TO APPEAR ON THE INMEDIATE PACKAGE (LABEL ON VIAL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Readycef 50 mg/ml suspension for injection for swine and cattle
Ceftiofur (as ceftiofur hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as ceftiofur hydrochloride) 50 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100ml
250 ml

5. TARGET SPECIES

Swine and cattle

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use in swine and Subcutaneous use in cattle.
Shake well before use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Swine: Meat and offal: 5 days.

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

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet before use.

10. EXPIRY DATE

EXP: end MM/YY
Shelf-life after first opening of the immediate packaging: 28 days.

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25º C.
Protect from light
Do not refrigerate or freeze
Keep the container in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal products or waste material 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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.
Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès (Barcelona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

17. MANUFACTURER'S BATCH NUMBER

Batch

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARDBOARD CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

READYCEF 50 mg/ml suspension for injection for swine and cattle
Ceftiofur (as ceftiofur hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as ceftiofur hydrochloride) 50 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

1 vial of 100ml
1 vial of 250 ml

5. TARGET SPECIES

Swine and cattle

6. INDICATION(S)

Swine:
Treatment of bacterial respiratory disease associated with *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Streptococcus suis* sensitive to ceftiofur hydrochloride.

Cattle:
For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica* (formerly *Pasteurella haemolytica), Pasteurella multocida* and *Histophilus somni* (former *Haemophilus somnus*) sensitive to ceftiofur hydrochloride.

For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* (*Porphyromonas asaccharolytica*) sensitive to ceftiofur hydrochloride.

For the 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 hydrochloride. The indication is restricted to cases where treatment with another antimicrobial has failed.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use in swine and Subcutaneous use in cattle
Shake well before use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Swine: Meat and offal: 5 days.

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

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet before use. Take care to avoid accidental self injection.

10. EXPIRY DATE

EXP : end MM/YY
Shelf-life after first opening of the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25º C.
Protect from light
Do not refrigerate or freeze
Keep the container in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal products or waste material 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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Calier, S.A.
Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès (Barcelona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

17. MANUFACTURER'S BATCH NUMBER

Batch

PACKAGE LEAFLET

READYCEF 50 mg/ml suspension for injection for swine 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
Laboratorios Calier, S.A.
Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès (Barcelona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

READYCEF 50 mg/ml suspension for injection for swine and cattle

Ceftiofur (as ceftiofur hydrochloride)

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

Each ml contains:
Active substance:
Ceftiofur (as ceftiofur hydrochloride) .....50 mg

White to white-cream coloured oily suspension

4. INDICATION(S)

Swine:

Treatment of bacterial respiratory disease associated with *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Streptococcus suis* sensitive to ceftiofur hydrochloride.

Cattle:

For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica* (formerly *Pasteurella haemolytica), Pasteurella multocida* and *Histophilus somni* (former *Haemophilus somnus*) sensitive to ceftiofur hydrochloride.

For the treatment of acute interdigital necrobacillosis (panaritium, foot rot), associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus* (*Porphyromonas asaccharolytica*) sensitive to ceftiofur hydrochloride.

For the 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 hydrochloride. 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 ß-lactam antibiotics or to any of the excipients.

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

Do not inject intravenously.

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

6. ADVERSE REACTIONS

In swine, 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.

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.

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

7. TARGET SPECIES

Swine and cattle

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

Swine:
3 mg ceftiofur /kg bw/day for 3 days by intramuscular injection, i.e. 1 ml of the veterinary medicinal product /16 kg bw / day.

Cattle:
Treatment of respiratory disease: 1 mg ceftiofur /kg bw/day for 3 to 5 days by subcutaneous injection, i.e. 1 ml of the veterinary medicinal product /50 kg bw / day.
Treatment of acute interdigital necrobacillosis: 1 mg ceftiofur /kg bw/day for 3 days by subcutaneous injection, i.e. 1 ml of the veterinary medicinal product /50 kg bw / day.
Acute post-partum metritis within 10 days after calving: 1 mg ceftiofur / kg bw / day for 5 consecutive days by subcutaneous injection, i.e. 1 ml of the veterinary medicinal product / 50 kg bw/ day.
Subsequent injections must be given at different sites.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

Before use shake the bottle for a minute or until the product appears adequately resuspended.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
100 ml vials can only be broached a maximum of 20 times. 250 ml vials can only be broached a maximum of 50 times

9. ADVICE ON CORRECT ADMINISTRATION
None

10. WITHDRAWAL PERIOD
Swine: Meat and offal: 5 days.

Cattle: Meat and offal: 8 days.

Milk: zero days.

11. SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.

Do not store above 25°C.
Do not use after the expiry date stated on the carton.
Shelf-life after first broaching of the container: 28 days.

Protect from light

Do not refrigerate or freeze

Keep the container in the outer carton

12. SPECIAL WARNING(S)

Special precautions for use in animals

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 in the SPC, may increase the prevalence of resistance. The product should only be used based on susceptibility testing.

The product 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.

In case of hypersensitivity or if you have been warned not to use these products any contact with the product should be avoided.
Take care to avoid accidental self injection.

In the case of self-injection or following exposure and development of symptoms such as skin rash, seek medical advice immediately and show the package leaflet to the physician.

Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Interaction with other medicinal products and other forms of interaction
The bactericidal properties of β-lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines)

Overdose (symptoms,emergency procedures,antidotes), if necessary
The low toxicity of ceftiofur has been demonstrated in swine 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 product must not be mixed with other veterinary medicinal products.

Use during pregnancy and lactation
Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects or of abortion. Safety has not been established in the target species during pregnancy. Use only according to the benefit/risk assessment by the responsible veterinarian.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal products or waste material 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

Box with 1 clear glass vial of 100ml.
Box with 1 clear glass vial of 250ml.

“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.”