PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

CARDBOARD BOX AND LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EFICUR® 50 mg/ml suspension for injection for pigs and cattle
Ceftiofur

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:
Ceftiofur ..... 50 mg (as Ceftiofur Hydrochloride)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml
10 x 10 ml
12 x 10 ml

5. TARGET SPECIES

Pigs and cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular for pigs and subcutaneous for cattle
Shake the bottle well before use to bring the product back into suspension
Read the package leaflet before use

8. WITHDRAWAL PERIOD

Pigs:
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 for user warnings.
Ceftiofur may constitute a risk to public health due to spread of antimicrobial resistance.

10. EXPIRY DATE

EXP
Shelf life after first broaching the container: 28 days
Once broached, use by ……..

11. SPECIAL STORAGE CONDITIONS

Glass and PET bottles
Do not store above 25ºC
Do not refrigerate or freeze.

PET bottles
Keep the PET bottles in the outer carton in order to protect from light

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

Dispose of waste material 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

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona) Spain
Tel. (972) 43 06 60

Local Representative:
HIPRA UK AND IRELAND, Ltd.
Innovation Center
BioCity Nottingham
Pennyfoot Street
Nottingham
NG1 1GF - UNITED KINGDOM
e-mail: ukandireland@hipra.com

16. MARKETING AUTHORISATION NUMBER(S)

UK only: Vm 17533/4010. POM-V
IE only: VPA. 10846/006/001 POM

17. MANUFACTURER'S BATCH NUMBER

Batch

AN: 01509/2015
Revised: February 2016

PACKAGE LEAFLET FOR:
EFICUR® 50 mg/ml suspension for injection for pigs and cattle
Ceftiofur

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:
LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135
17170 Amer (Girona) Spain
Tel. (972) 43 06 60

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EFICUR® 50 mg/ml suspension for injection for pigs and cattle
Ceftiofur

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

1 ml contains:
Ceftiofur ..... 50 mg (as Ceftiofur Hydrochloride)

EFICUR is a white or yellowish oily suspension

4. INDICATION(S)

Infections associated with bacteria sensitive to ceftiofur:
Pigs:
- Treatment of bacterial respiratory disease associated with *Pasteurella multocida*, *Actinobacillus pleuropneumoniae* and *Streptococcus suis*.

Cattle:
- For the treatment of bacterial respiratory disease associated with *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni.*.
- For the treatment of acute interdigital necrobacillosis (panaritium, foot rot) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus (Porphyromonas asaccharolytica).*
- 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* (restricted to cases where treatment with another antimicrobial has failed).

5. CONTRAINDICATIONS

Do not administer to animals previously found to be hypersensitive to ceftiofur and other β-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

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 package leaflet, 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 by intramuscular injection, i.e. 1 ml of EFICUR/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 EFICUR/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 EFICUR/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 EFICUR/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.

9. ADVICE ON CORRECT ADMINISTRATION

- Shake the bottle well before use to bring the product back into suspension. In the case of 250 ml glass bottle, remove the protector before shaking. The coloration of the glass bottle may not be uniform making it difficult to determine when the product is in suspension. Following shaking the absence of sediment can be confirmed most readily by inverting the bottle and viewing the contents through the base of the bottle.
- Should any apparent growth or discolouration occur, the product should be discarded.
- To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD

Pigs:
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.
Glass and PET bottles
Do not store above 25°C
Do not refrigerate or freeze
PET bottles
Keep the PET bottles in the outer carton in order to protect from light
Do not use EFICUR after the expiry date stated on the label after Exp.
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 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)

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.
People with known hypersensitivity to penicillins or cephalosporins should avoid contact with the product.
In the case of accidental self-injection or following exposure, if you develop symptoms such as a skin rash, seek medical advice immediately and show the package

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

Special precautions for use in animals
In case of the occurrence of allergic reaction the treatment should be withdrawn.

Ceftiofur selects for resistant strains such as bacteria carrying extended spectrum betalactamases (ESBL) and may constitute a risk to human health if these strains disseminate to humans e.g. via food. For this reason, ceftiofur 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 first line treatment.

Ceftiofur is intended for treatment of individual animals. Do not use 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 (see Section 4 Indications).

Pregnancy:
Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of the veterinary medicinal product has not been established during pregnancy. 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 β–lactams are neutralised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracyclines).

Use of Eficur 50 mg/ml suspension for injection may constitute a risk to public health due to spread of antimicrobial resistance.

Ceftiofur 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, ceftiofur should only be used based on susceptibility testing.
Do not use as prophylaxis in case of retained placenta.

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

Pack sizes:
Cardboard box with 1 glass bottle of 50 ml.
Cardboard box with 1 glass bottle of 100 ml.
Cardboard box with 1 glass bottle of 250 ml.
Cardboard box with 10 glass bottles of 100 ml.
Cardboard box with 12 glass bottles of 100 ml.

Cardboard box with 1 PET bottle of 50 ml.
Cardboard box with 1 PET bottle of 100 ml.
Cardboard box with 1 PET bottle of 250 ml.

Not all pack sizes may be marketed.

FOR ANIMAL TREATMENT ONLY
TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION
UK only: Vm 17533/4010. POM-V: Prescription Only Medicine
IE only: VPA 10846/006/001. POM: Prescription Only Medicine

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