ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with one 100ml polyethylene terephthalate (PET) vial
Cardboard box with one 250ml polyethylene terephthalate (PET) vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACTIONIS 50 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Ceftiofur (as ceftiofur hydrochloride) 50 mg/ml

3. PACKAGE SIZE

100ml
250ml

4. TARGET SPECIES

Pigs and cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pigs: Intramuscular use. Cattle: Subcutaneous use.

7. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: Meat and offal: 6 days.
Milk: zero hours.

Pigs: Meat and offal: 6 days.

8. EXPIRY DATE

Exp, {mm/yyyy}
Once broached, use within 28 days
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.

14. MARKETING AUTHORISATION NUMBER

Vm 31592/3003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100ml polyethylene terephthalate (PET) vial label
250ml polyethylene terephthalate (PET) vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACTIONIS 50 mg/ml suspension for injection

2. STATEMENT OF ACTIVESUBSTANCES

Ceftiofur (as ceftiofur hydrochloride) 50 mg/ml

3. TARGET SPECIES

Pigs and cattle

4. ROUTES OF ADMINISTRATION

Pigs: Intramuscular use. Cattle: Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle: Meat and offal: 6 days.
Milk: zero hours.

Pigs: Meat and offal: 6 days.

6. EXPIRY DATE

Exp {mm/yyyy}
Once broached, use within 28 days.
Once broached, use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAMEOF THE MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Actionis 50 mg/ml suspension for injection for pigs and cattle.

2. Composition

Each ml contains:

Ceftiofur (as ceftiofur hydrochloride) 50 mg

White to pale yellow oily suspension

3. Target species

Pigs and cattle.

4. Indications for use

Infections associated with bacteria sensitive to ceftiofur:

Pigs:
For the 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 Prevotella melaninogenica (*Porphyromonas asaccharolytica*).
For treatment of the bacterial component of acute post-partum (puerperal) metritis within 10 days after calving associated with *Escherichia coli*, *Trueperella 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 or to any of the excipients.
Do not use in cases of known resistance to ceftiofur or other beta-lactam antibiotics.
Do not inject intravenously.

6. Special warnings

Special precautions for safe use in the target species:

This product does not contain an antimicrobial preservative.

The product 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*.
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.
Shake vigorously before use for 1 minute or until the complete resuspension of the product.

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

Penicillin's and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion, or skin contact. Hypersensitivity to penicillin's may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this veterinary medicinal 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 taking all recommended precautions.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
If you develop symptoms following exposure such as 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.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.
Laboratory studies have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects.

Interaction with other medicinal products and other forms of interaction:

The bactericidal properties of cephalosporins are antagonized by simultaneous use of bacteriostatic antibiotics (macrolides, sulfonamides and tetracyclines). Aminoglycosides may have a potentiating effect on cephalosporins.

Overdose:

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.

Special restrictions for use and special conditions for use:

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Pigs and cattle:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports)
Hypersensitivity reaction[1], Allergic reaction (e.g. skin reaction, anaphylaxis)[2]

[1] Unrelated to dose.
[2] In this case, the treatment should be withdrawn.

Pigs:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports)
Injection site reaction (e.g. discoloration of the fascia or fat)[1]

[1] Mild reactions, discoloration can persist in some animals for up to 20 days after injection.

Cattle:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports)
Injection site reaction (e.g. as tissue oedema, discoloration[1])[2]

[1] Subcutaneous tissue and/or fascial surface of the muscle.
[2] Mild inflammatory reactions, clinical resolution is reached in most animals by 10 days after injection although slight tissue discoloration may persist for 28 days or more.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.
[To be completed in accordance with national requirements after conclusion of the MRP/DCP/SRP.]

8. Dosage for each species, routes and method of administration

Intramuscular or subcutaneous use.

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.
In case of acute post-partum metritis, additional supportive therapy might be required in some cases.
Not more than 5 ml should be administered at any one intramuscular injection site in pigs or 7 ml at any one subcutaneous injection site in cattle. Subsequent injections must be given at different sites.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
Shake vigorously before use for 1 minute or until the complete resuspension of the product.
The user should select the most appropriate vial size.

10. Withdrawal periods

Cattle:
Meat and offal: 6 days.
Milk: zero hours.

Pigs:
Meat and offal: 6 days.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.
Shelf-life after first opening the inmediate packaging: 28 days

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

14. Marketing authorisation numbers and pack sizes

Vm 31592/3003

Polyethylene terephthalate (PET) vial of 100ml or 250ml with a type I nitrile-chlorobutyl rubber stopper and flip-off cap.

Pack sizes:
Cardboard box with 1 vial of 100ml.
Cardboard box with 1 vial of 250ml.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing Authorisation Holder:

Laboratorios SYVA S.A.
C/ Marqués de la Ensenada, 16
28004 Madrid
Spain

Manufacturer responsible for batch release:

Laboratorios SYVA S.A.
Avenida del Párroco Pablo Díez 49-57
San Andrés del Rabanedo
24010 LEÓN
SPAIN

Local representative and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.

Deutschland:
Local representative:
BELA-PHARM GMBH & CO. KG
Lohner Str.19
D-49377 Vechta
Tel: + 04441 873 0

Contact details to report suspected adverse reactions:
BELA-PHARM GMBH & CO. KG
Tel: +49 4441 873 555
E-mail: pharmacovigilance@bela-pharm.com

España:
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
+34 987 800 800
E-mail: farmacovigilancia@syva.es

Polska:
Local representative:
Grabikowski-Grabikowska PPHU „INEX" Sp.j.
ul. Białostocka 12, 11-500 Giżycko,
Polska Tel.: +48 87 429 17 19

Contact details to report suspected adverse reactions:
Grabikowski-Grabikowska PPHU „INEX" Sp.j.
Tel.: + 48 795 128 650
E-mail: bezpieczenstwo@biofaktor.pl

Portugal:
Contact details to report suspected adverse reactions:
Laboratorios Syva S.A.
Parque Tecnológico De León
Calle Nicostrato Vela M15-M16
24009 LEÓN
ESPAÑA
+351 219 747 934
E-mail: syva.portugal@syva.pt

Italia:
Local representative:
IZO s.r.l. a socio unico
Via San Zeno 99/A
25124 Brescia - Italia
Tel: + 39 030 2420583

Contact details to report suspected adverse reactions:
IZO s.r.l. a socio unico
Tel: + 39 030 2420583
E-mail: pharmacovigilanza@izo.it

Magyarország:
Local representative:
Alpha-Vet Állatgyógyászati Kft.
8000 Székesfehérvár, Homoksor 7.
Tel.: + 36-22-534500

Contact details to report suspected adverse reactions:
Alpha-Vet Állatgyógyászati Kft.
Tel.: +36 30 5011484
E-mail: kun.csaba@alpha-vet.hu

United Kingdom (Northern Ireland):
Local representative:
FORTE Healthcare Ltd,
Block 3, Unit 9,
CityNorth Business Campus,
Stamullen, Co. Meath. K32 D990
Ireland

Contact details to report suspected adverse reactions:
FORTE Healthcare Ltd
Tel: +353 1 841 7666
E-mail:
pharmacovigilance@fortehealthcare.com

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