

PARTICULARS TO APPEAR ON THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

Box with one 100ml glass vial.
Box with one 250ml glass vial
Box with one 100ml polyethylene terephthalate (PET) vial.
Box with one 250ml polyethylene terephthalate (PET) vial.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ACTIONIS 50 mg/ml suspension for injection for pigs and cattle.
Ceftiofur (as ceftiofur hydrochloride)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ceftiofur (as hydrochloride) 50 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

100ml
250ml

5. TARGET SPECIES

Pigs and cattle.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD

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

Pigs: Meat and offal: 6 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

User Warnings: Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}

Once opened, use by:

Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.

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 SYVA S.A.U.
Avda. Párroco Pablo Díez,
49-57 (24010) León
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 31592/4004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

10. EXPIRY DATE

EXP {month/year}

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 31592/4004

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET FOR:
ACTIONIS 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:

Laboratorios SYVA S.A.U.
Avda. Párroco Pablo Díez,
49-57 (24010) León
Spain
Tel: 0034 987800800
Fax: 0034 987802452
Email: mail@syva.es

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Actionis 50 mg/ml suspension for injection for pigs and cattle.
Ceftiofur (as ceftiofur hydrochloride)

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

Each ml of white to pale yellow oily suspension contains:

ceftiofur (as hydrochloride) 50 mg

4. INDICATION(S)

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 *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 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.

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, or allergic reactions (e.g. skin reactions, anaphylaxia) may occur in very rare cases. 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 very rare cases 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 in very rare cases. 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 displaying adverse reaction(s) during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals).
- Rare (more than 1 but less than 10 animals in 10,000 animals).
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this 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 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.

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

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

Shake vigorously before use during 1 minute or until the complete resuspendability of the product.

The user should select the most appropriate vial size.

10. WITHDRAWAL PERIOD

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 and vial after "EXP". The expiry date refers to the last day of the 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 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)

Special precautions for use in animals:

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 herd 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 during 1 minute or until the complete resuspendability 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:

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.

Handle this product with great care to avoid exposure taking all recommended precautions.

Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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:

Laboratory studies have not produced any evidence of a teratogenic, foetotoxic or maternotoxic effects. The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Use only accordingly to the 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, sulfonamides and tetracyclines).

Aminoglycosides may have a potentiating effect on cephalosporins.

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 overdoses.

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 or pharmacist 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

15. OTHER INFORMATION

To be supplied only on veterinary prescription

Pack Sizes: Box with one 100ml vial,
 Box with one 250ml vial,

Not all pack sizes may be marketed.



Approved 12 April 2017