PACKAGE LEAFLET FOR

Cemay 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 Maymó, S.A.U.
Vía Augusta 302. 08017
Barcelona (Spain).

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cemay 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)

Composition
One ml contains:
Ceftiofur (as ceftiofur hydrochloride) 50 mg
Excipients, q.s. ..... 1 ml

4. INDICATION(S)

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*, *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*, *Trueperella pyogenes* (*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 case of hypersensitivity to the active substance, to other beta-lactam antibiotics or to any of the excipients
Do not inject intravenously.
Do not use in poultry (including eggs) due to risk of spread antimicrobial resistance to humans.
Do not use in cases where resistance to ceftiofur or to other cephalosporins or beta-lactam antibiotics has occurred

6. ADVERSE REACTIONS

In case of the occurrence of allergic reaction the treatment should be withdrawn.

In very rare cases the following adverse reactions may occur:
- Hypersensitivity reactions unrelated to dose.

- Allergic reactions (e.g. skin reactions, anaphylaxia). In case of the occurrence of allergic reaction the treatment should be withdrawn

- In pigs, mild reactions at the injection site, such as minimal residual lesions in the intermuscular connective tissue consisting of round clear areas, have been observed in some animals for up to 20-22 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 was observed at most injection sites by 10 days after injection, although slight tissue discoloration may persist for 32 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: intramuscular use
3 mg ceftiofur /kg bw/day, corresponding to 1 ml/16 kg bw/day for 3 days via. Cattle: subcutaneous use
- Respiratory disease: 1 mg ceftiofur /kg bw/day, corresponding to 1 ml/50 kg bw/day for 3 to 5 days.
- Acute interdigital necrobacillosis: 1mg/kg bw/day, corresponding to 1 ml/50 kg bw/day for 3 consecutive days.

Acute post-partum metritis within 10 days after calving: 1 mg/kg bw/day, corresponding to 1 ml/50 kg bw/day for 5 consecutive days. In case of acute post-partum metritis, additional supportive therapy might be required in some cases.

A maximum volume of 6 ml may be administered in each injection site.

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 to avoid underdosing.
As the vial can not be broached more than 40 times, the user should choose the more appropriate vial size.
Shake the bottle well for 30 seconds before use to bring the veterinary medicinal product back into suspension.

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

Do not use this veterinary medicial product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month

Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNINGS

Special warnings for each target species
None

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

Use of CEMAY may constitute a risk to public health due to spread of antimicrobial resistance.
Cemay 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 such resistance. Whenever possible, Cemay should only be used based on susceptibility testing.

Cemay 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.

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.
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.
Handle this product with great care to avoid exposure. Wash hands after use.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Use during pregnancy, lactation or lay
Studies in laboratory species have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. Safety has not been established in the target species 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 antagonised by simultaneous use of bacteriostatic antibiotics (macrolides, sulphonamides and tetracycline).

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 be not disposed of via wastewater. Ask your veterinary surgeon 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

05/2024

15. OTHER INFORMATION

Package sizes:
Cardboard box with 1 bottle of 100 ml
Cardboard box with 1 bottle of 250 ml

Not all pack sizes may be marketed.