ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan 25 mg/ml suspension for injection for cattle and pigs
Cefquinome

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Cefquinome 25 mg
(equivalent to 29.64 mg cefquinome sulfate)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

1 x 50 ml
6 x 50 ml
12 x 50 ml
1 x 100 ml
6 x 100 ml,
12 x 100 ml
1 x 250 ml
6 x 250 ml,
12 x 250 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection.
Shake the vial well before using.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Meat and offal: 5 days
Milk: 24 hours

Pigs:
Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

User warnings:
Cephalosporins may occasionally cause severe allergic reactions. Read package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening of the immediate packaging: 28 days

[only 1 x 50ml, 1 x 100 ml and 1 x 250 ml]
Once opened use by……

11. SPECIAL STORAGE CONDITIONS

Protect from light.

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

Disposal: read package leaflet.

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

Livisto Int'l S.L.
Avda. Universitat Autònoma 29
08290 Cerdanyola del Vallès
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4003

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan 25 mg/ml suspension for injection for cattle and pigs
Cefquinome

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Cefquinome 25 mg
(equivalent to 29.64 mg cefquinome sulfate)

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection.
Shake the vial well before using.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Cattle:
Meat and offal: 5 days
Milk: 24 hours

Pigs:
Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening of the immediate packaging: 28 days
Once opened use by……

11. SPECIAL STORAGE CONDITIONS

Protect from light.

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

Disposal: read package leaflet.

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

Livisto Int'l S.L.
Avda. Universitat Autònoma 29
08290 Cerdanyola del Vallès
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4003

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

Qivitan 25 mg/ml suspension for injection for cattle and pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Livisto Int'l S.L.
Avda. Universitat Autònoma 29
08290 Cerdanyola del Vallès
Barcelona
Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
Esplugues de Llobregat
08950 Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Qivitan 25 mg/ml suspension for injection for cattle and pigs
Cefquinome

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

Each ml contains:

Active substance:
Cefquinome 25 mg
(equivalent to 29.64 mg cefquinome sulfate)

White to slightly yellowish suspension

4. INDICATION(S)

For the treatment of bacterial infections in cattle and pigs caused by the Gram positive and Gram negative microorganisms sensitive to cefquinome.

Cattle:
Respiratory disease caused by *Pasteurella multocida* and *Mannheimia haemolytica*.
Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot).

Acute *E.coli* mastitis with signs of systemic involvement.

Calves:
E.coli septicaemia in calves

Pigs:
For the treatment of bacterial infections of the lungs and respiratory tract caused by *Pasteurella multocida*, *Haemophilus parasuis*, *Actinobacillus pleuropneumoniae*, *Streptococcus suis* and other cefquinome-sensitive organisms.
Mastitis-Metritis-Agalactia syndrome (MMA) with involvement of *E.coli*, *Staphylococcus* spp., *Streptococcus* spp. and other cefquinome sensitive organisms.

Piglets:
Reduction of mortality in cases of meningitis caused by *Streptococcus suis*.
For the treatment of:
Arthritis caused by *Streptococcus* spp., *E. coli* and other cefquinome-sensitive organisms.
Epidermitis (mild or moderate lesions) caused by *Staphylococcus hyicus*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to ß-lactam antibiotics, or to any of the excipients.
Do not administer to animals less than 1.25 kg body weight.
Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans.

6. ADVERSE REACTIONS

Use of the veterinary medicinal product may result in localized tissue reaction. Tissue lesions are repaired 15 days after the last administration of the veterinary medicinal product.
Hypersensitivity reactions to cephalosporins occur rarely.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle and pigs

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

For intramuscular injection.

Species	Indication	Dosage	Frequency
Cattle	Respiratory disease caused by *Pasteurella multocida* and *M. haemolytica* Digital dermatitis, infectious bulbar necrosis and acute interdigital necrobacillosis (foul in the foot)	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 3 to 5 consecutive days
	Acute *E. coli* mastitis with signs of systemic involvement	1 mg cefquinome/kg bw (2 ml/50 kg bw)	Once daily for 2 consecutive days
Calves	*E. coli* septicaemia	2 mg cefquinome/kg bw (4 ml/50 kg bw)	Once daily for 3 to 5 consecutive days
Pigs	Respiratory disease	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 3 consecutive days.
	MMA	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 2 consecutive days.
Piglets	Meningitis Arthritis Epidermitis	2 mg cefquinome/kg bw (2 ml/25 kg bw)	Once daily for 5 consecutive days

Studies have indicated the advisability of giving second and subsequent injections at different injection sites. The preferred injection site is in the muscular tissue of the mid neck.
To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.
Shake the vial well before using.

9. ADVICE ON CORRECT ADMINISTRATION

The veterinary medicinal product does not contain an antimicrobial preservative.
Swab the septum before removing each dose. Use a dry sterile needle and syringe.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes, for example when treating piglets.

When treating groups of animals, use a draw-off needle.
The rubber stopper of the vial may be safely punctured up to 50 times.

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: 5 days
Milk: 24 hours

Pigs:
Meat and offal: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from light.

Shelf-life after first opening of the immediate packaging: 28 days
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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 vial should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:

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

The use of cefquinome should be restricted to appropriate use according to the labelled indications in the target animal species.

Use of Qivitan 25 mg/ml may constitute a risk to public health due to spread of antimicrobial resistance.

Qivitan 25 mg/ml 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 such resistance. Whenever possible, Qivitan 25 mg/ml should only be used based on susceptibility testing.

Inappropriate use of the product may increase the prevalence of bacteria resistant to cefquinome and may decrease the effectiveness of treatment with other beta lactam antibiotics, due to the potential for cross resistance.

Qivitan 25 mg/ml is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programs. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks according to the approved conditions of use.

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

Cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross sensitivity 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 sensitized, or if you have been advised not to work with such preparations.
- Handle this veterinary medicinal product with great care to avoid exposure, taking all recommended precautions.
- 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.

Wash hands after use.

Pregnancy and lactation:
Laboratory studies in rat and rabbit have not produced any evidence of teratogenic, embryotoxic or maternotoxic effects. The safety of the product has not been assessed in cow and sow during pregnancy. Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Due to an undesirable pharmacodynamic interaction, do not use cefquinome simultaneously with pharmaceuticals acting bacteriostatically.

Overdose (symptoms, emergency procedures, antidotes):
Overdoses of 20 mg/kg/day in cattle and 10 mg/kg/day in pigs and piglets have been well tolerated.

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

Any unused veterinary medicinal product or waste materials 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

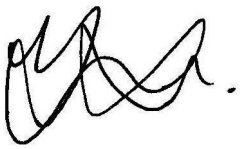
February 2022

15. OTHER INFORMATION>

Pack sizes:
1 x 50 ml, 6 x 50ml, 12 x 50 ml
1 x 100 ml, 6 x 100 ml, 12 x 100 ml
1 x 250 ml, 6 x 250 ml, 12 x 250 ml

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.



Approved: 23 February 2022