ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORINJECT 300 mg/ml solution for injection for cattle and
Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains

Florfenicol .....300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:
Meat and offal: by IM: 30 days
by SC: 44 days

Milk: Not authorised for use in cattle producing milk for human consumption, including during the dry period.

Pigs:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 28 days.
Once broached/opened, use by _____

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to 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

LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès,
(Barcelona) Spain

16. MARKETING AUTHORISATION NUMBER

Vm 20634/4007

17. MANUFACTURER'S BATCH NUMBER

Batch number

PARTICULARS TO APPEAR ON THE INNER PACKAGE

{LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORINJECT 300 mg/ml solution for injection for cattle and
Florfenicol

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains
Florfenicol .....300 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Cattle and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle:
Meat and offal: by IM: 30 days
by SC: 44 days

Milk: Not authorised for use in cattle producing milk for human consumption, including during the dry period.

Pigs:
Meat and offal: 18 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 28 days.
Once broached/opened, use by _____

11. SPECIAL STORAGE CONDITIONS

Keep the bottle in the outer carton in order to 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

LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès,
(Barcelona) Spain

16. MARKETING AUTHORISATION NUMBER

20634/4007

17. MANUFACTURER'S BATCH NUMBER

Batch number

B. PACKAGE LEAFLET

PACKAGE LEAFLET
FLORINJECT 300 mg/ml solution for injection for cattle and pigs

Florfenicol

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:
LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla del Ramassà)
Les Franqueses del Vallès,
(Barcelona) Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORINJECT 300 mg/ml solution for injection for cattle and pigs

Florfenicol

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

Each ml contains

Active substance:
Florfenicol 300 mg

Clear slightly yellowish solution.

4. INDICATION(S)

Cattle:
Treatment and metaphylaxis of respiratory tract infections in cattle due to *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni,* susceptible to florfenicol.
The presence of the disease in the herd should be established before metaphylaxis.

Pigs:
Treatment of acute outbreaks of respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

5. CONTRAINDICATIONS

Do not use in adult bulls and boars intended for breeding purposes.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

In cattle, a decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.

Administration of the product by the intramuscular and subcutaneous routes may cause inflammatory lesions at injection site which persist for 14 days.

On very rare occasions, anaphylactic reactions have been reported in cattle.
In pigs, commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/oedema which may affect 50% of the animals. These effects can be observed for one week. Under field conditions approximately 30% of treated pigs presented with pyrexia (40°C) associated with either moderate depression or moderate dyspnea a week or more after administration of the second dose.

Transient swelling lasting up to 5 days may be observed at the site of injection. Inflammatory lesions at the injection site may be seen up to 28 days.

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

Cattle: Intramuscular or subcutaneous injection
Pigs: Intramuscular injection

Cattle:
Treatment

IM route: 20 mg florfenicol/kg bodyweight (1ml of the product/15kg) to be administered twice 48 hours apart using a 16 gauge needle.

SC route: 40 mg florfenicol/kg bodyweight (2ml of the product/15kg) to be administered once only using a 16 gauge needle.

Metaphylaxis
SC route: 40 mg florfenicol/kg bodyweight (2ml of the product/15kg) to be administered once only using a 16 gauge needle.

Pigs:
15 mg florfenicol/kg bodyweight (1 ml of the product / 20 kg) by intramuscular injection twice at 48 hour intervals using a 16-gauge needle.

The dose volume given at any one injection site should not exceed 10 ml for both routes of administration (intramuscular and subcutaneous) in cattle and 3 ml in pigs. The injection should only be given in the neck in both target species.

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

It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection. If clinical signs of respiratory disease persist 48 hours after the last injection or if relapse occurs, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved.

Swab septum before removing each dose. Use a dry sterile needle and syringe

Do not broach the vial more than 25 times.

9. ADVICE ON CORRECT ADMINISTRATION

It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours after the second injection. If clinical signs of respiratory disease persist 48 hours after the last injection, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

10. WITHDRAWAL PERIOD

Cattle:
Meat and offal: by IM: 30 days
by SC: 44 days

Milk: Not authorised for use in cattle producing milk for human consumption, including during the dry period.

Pigs:
Meat and offal: 18 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the bottle in the outer carton in order to protect from light.
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.
Do not use after the expiry date stated on the label.
Shelf-life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special precautions for use

This veterinary product does not contain an antimicrobial preservative.

Special precautions for use in animals

Do not administer to piglets of less than 2 kg.
Use of product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official national and regional antimicrobial policies should be taken into account when the product is used.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to florfenicol and may decrease the effectiveness of treatment with other antimicrobials due to the potential for cross-resistance.

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

This product may cause hypersensitivity (allergy).
People with known hypersensitivity to florfenicol or propylene glycol should avoid contact with the product.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice taking the label or package leaflet with you to show the physician.
Avoid skin or eye contact with the product. In case of contact with the skin or eyes, rinse the affected area immediately with plenty of water. Wash hands after use.

Use during pregnancy and lactation

Laboratory studies have not produced any evidence of teratogenic or foetotoxic effects.

Cattle
The safety of the veterinary medicinal product has not been established during pregnancy.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian

Pigs
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
It is not recommended to use the veterinary medicinal product in pigs during pregnancy and lactation.

Overdose (symptoms, emergency procedures, antidotes):
Cattle:
No symptoms other than those noted in section 6.

Pigs:
After administration of 3 times the recommended dose or more a reduction in feeding, hydration and weight gain has been observed.

After administration of 5 times the recommended dose or more vomiting has also been noted.

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 products should be disposed of in accordance with local requirements

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2019

15. OTHER INFORMATION

Approved 18 December 2019