ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORINJECT 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Florfenicol .....300 mg

3. PACKAGE SIZE

250 ml

4. TARGET SPECIES

Cattle and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: Intramuscular or subcutaneous injection.
Pigs: Intramuscular injection.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle:
Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days.
by SC (at 40 mg/kg bodyweight, once): 44 days.

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

Pigs:
Meat and offal: 18 days.

8. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 28 days.
Once broached/opened, use by _____

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

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. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBER

Vm 20634/3003

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{ADHESIVE LABEL ON 250 ML VIAL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLORINJECT 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Florfenicol .....300 mg

3. TARGET SPECIES

Cattle and pigs.

4. ROUTES OF ADMINISTRATION

Solution for injection

Cattle: Intramuscular or subcutaneous injection.
Pigs: Intramuscular injection.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Cattle:
Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days.
by SC (at 40 mg/kg bodyweight, once): 44 days.

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

Pigs:
Meat and offal: 18 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 28 days.
Once broached/opened, use by _____

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains

Active substance:

Florfenicol	300 mg

Excipients:

N-methyl pyrrolidone	250 mg

Clear slightly yellowish solution.

3. Target species

Cattle and pigs.

4. Indications for use

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. Special warnings

Special precautions for safe use in the target species:
Do not administer to piglets of less than 2 kg.
Use of the veterinary medicinal 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 veterinary medicinal product is used.

Use of the veterinary medicinal 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.
An antibiotic with a lower risk of antimicrobial resistance selection (lower AMEG category) should be used for first line treatment where susceptibility testing suggests the likely efficacy of this approach.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause hypersensitivity (allergy).
People with known hypersensitivity to florfenicol or propylene glycol should avoid contact with the veterinary medicinal product.
Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.
Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid skin or eye contact with the veterinary medicinal product. In case of contact with the skin or eyes, rinse the affected area immediately with plenty of water. Wash hands after use.

Special precautions for the protection of the environment:
The use of this veterinary medicinal product may pose a risk for terrestrial plants, cyanobacteria and groundwater organisms.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy, lactation, or in animals intended for breeding. Studies in laboratory animals have not revealed any evidence of embryo- or foetotoxic potential for florfenicol. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:
Do not use in adult bulls and boars intended for breeding (see section 5).

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose**:**
Cattle:
No symptoms other than those noted in section 7.

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.

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

7. Adverse events

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction (severe allergic reaction)
Undetermined frequency:	Reduced food intake[1] Pasty stool[1,3] Injection site inflammation[2]

[1] may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.
[2] persists for 14 days.
[3] transient.

Pigs:

Very common (>1 animal / 10 animals treated):	Diarrhoea[4] Erythema (redness) / oedema (swelling)[5,6] Pyrexia (fever)[7] Depression[7] Dyspnoea (difficulty breathing)[7]
Undetermined frequency:	Injection site swelling[4,8] Injection site inflammation[9]

[4] transient.
[5] peri-anal and rectal.
[6] can be observed for one week.
[4] pyrexia is associated with either moderate depression or moderate dyspnea. Observed a week or more after administration of the second dose.
[8] lasting up to 5 days.
[9] may be seen up to 28 days.

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.

8. Dosage for each species, routes 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.

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
Wipe the stopper before removing each dose. Use a dry, sterile syringe and needle.
Do not broach the vial more than 25 times.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

10. Withdrawal periods

Cattle:
Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days.
by SC (at 40 mg/kg bodyweight, once): 44 days.

Milk: Not authorised for use in animals 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 vial in the outer carton in order to protect from light.
When the immediate packaging 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 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 the month.

Shelf life after first opening the container: 28 days

12. Special precautions for disposal

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

This veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish and other aquatic organisms.

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.

14. Marketing authorisation numbers and pack sizes

Vm 20634/3003

Package size:
Cardboard box with 1 vial of 250 ml

15. Date on which the package leaflet was last revised

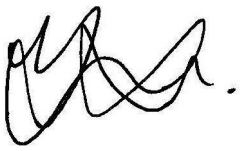
November 2023

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Local representatives and contact details to report suspected adverse reactions:



Approved: 18 March 2024