ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flordofen 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Florfenicol 300 mg/ml

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: Subcutaneous and intramuscular use.
Pigs: Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal by IM: 30 days
by SC: 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 container: 28 days.
Once broached use by …

9. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C.
Keep the vial in the outer carton in order to protect from light.
Pregnant women should take extra care when handling this product. See full user warnings for details.

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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 28365/3005

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flordofen 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Florfenicol 300 mg/ml

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

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

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal by IM: 30 days
by SC: 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 container: 28 days.
Once broached use by …

7. SPECIAL STORAGE PRECAUTIONS

Store below 25 °C. Keep the vial in the outer carton in order to protect from light.
Pregnant women should take extra care when handling this product. See full user warnings for details.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Flordofen 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 warnings:
This veterinary medicinal product does not contain an antimicrobial preservative.

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 leaflet may increase the prevalence of bacteria resistant to the 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:
People with known hypersensitivity to florfenicol, propylene glycol or polyethylene glycols should avoid contact with the veterinary medicinal product.
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 the hands after use.
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.

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 'Contraindications').

Overdose:
In swine 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.

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.

7. Adverse events

Adverse events

Cattle:

Undetermined frequency (cannot be estimated from the available data):	Reduced food intake, loose stool[1] Injection site inflammation[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reaction

[1] quick and complete recovery upon termination of treatment
[2] after intramuscular and subcutaneous injection; may persist for 14 days

Pigs:

Common (1 to 10 animals / 100 animals treated):	Diarrhoea, peri-anal and rectal erythema/oedema[3] Pyrexia (40°C), moderate depression, moderate dyspnoea[4]
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling[5] Injection site inflammation[6]

[3] can be observed for one week
[4] a week or more after administration of the second dose
[5] lasting up to 5 days
[6] lasting 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 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 use.
Pigs: Intramuscular use.

Cattle:
Treatment
IM route: 20 mg florfenicol / kg bodyweight (1 ml of the veterinary medicinal product / 15 kg) to be administered twice 48 hours apart using a 16-gauge needle.
SC route: 40 mg florfenicol / kg bodyweight (2 ml of the veterinary medicinal product / 15 kg) to be administered once only using a 16-gauge needle.

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

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

9. Advice on correct administration

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.

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 stopper of vial more than 25 times.

10. Withdrawal periods

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

Store below 25 °C.
Keep the vial in the outer carton in order to protect from light.
Shelf-life after first opening the immediate packaging: 28 days.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 how to dispose of medicines no longer required.
The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for fish and other aquatic organisms.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Box with 1 polypropylene vial of 250 ml.
Box with 1 colourless type II glass vial of 50 or 100 ml.
Box with 1 brown-coloured type II glass vial of 250 ml.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
Tel +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24
NL- 4941 VX Raamsdonksveer

<17. Other information

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Gavin Hall

Approved: 15 April 2026