PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Carton box for the 50, 100 and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Florfenicol 300 mg

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle and sheep.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For treatment:
Cattle: Intramuscular and subcutaneous use.
Sheep: Intramuscular use.
For metaphylaxis:
Cattle: Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal

Cattle:	IM use (20 mg/kg bodyweight, twice):	30 days.
	SC use (40 mg/kg bodyweight, once):	44 days.
Sheep:		39 days.

Milk
Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Do not refrigerate.
Protect from frost.

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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 06376/5053

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – Label for the 100 and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR 300 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Florfenicol 300 mg

3. TARGET SPECIES

Cattle and sheep.

4. ROUTES OF ADMINISTRATION

Treatment: Intramuscular and subcutaneous use.
Metaphylaxis: Subcutaneous use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal

Cattle:	IM use (20 mg/kg bodyweight, twice):	30 days.
	SC (40 mg/kg bodyweight, once):	44 days.
Sheep:		39 days.

Milk
Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

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

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Do not refrigerate.
Protect from frost.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

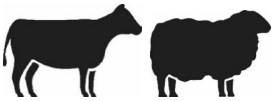
9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS – Label for the 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Florfenicol 300 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

NUFLOR 300 mg/ml solution for injection for cattle and sheep

2. Composition

Each ml contains:

Active substance:
Florfenicol 300 mg

Excipients:
N-methylpyrrolidone 250 mg

Clear, light yellow to straw-coloured, somewhat viscous solution.

3. Target species

Cattle and sheep.

4. Indications for use

Cattle:
Diseases caused by florfenicol susceptible bacteria.
Metaphylactic and therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni*. The presence of the disease in the herd should be established before metaphylactic treatment.

Sheep:
Treatment of ovine respiratory tract infection due to *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to florfenicol.

5. Contraindications

Do not use in adult bulls and rams intended for breeding purposes.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

None.

Special precautions for safe use in the target species:
The veterinary medicinal product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.

The safety of the veterinary medicinal product has not been established in sheep younger than 7 weeks of age.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to propylene glycol and polyethylene glycols should avoid contact with the veterinary medicinal product. In case of accidental contact with skin or eyes, rinse immediately with plenty of water.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of fetotoxic 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, Lactation and Fertility:
The safety of the veterinary medicinal product has not been established in cattle and sheep during pregnancy, lactation or in animals intended for breeding. 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.

Interaction with other medicinal products and other forms of interaction:
No data available.

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

Sheep: After administration of 3 times the recommended dose or more a transient reduction in feed and water consumption has been observed. Additional effects included an increased incidence of lethargy, emaciation and loose faeces.
Head tilt was seen after administration of 5 times the recommended dose and was considered most likely a result of irritation at the injection site.

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):	Reduced food intake[1]; Loose stool[1]; Injection site inflammation[2], Injection site lesion[2]; Anaphylaxis (severe allergic reaction).

[1] Quick and complete recovery upon termination of treatment.
[2] May persist for 14 days after intramuscular and subcutaneous administration.

Sheep:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Reduced food intake[1]; Injection site inflammation[2], Injection site lesion[2].

[1] Quick and complete recovery upon termination of treatment.
[2] Mild and may persist up to 28 days after intramuscular administration.

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: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

For treatment
Cattle:
Intramuscular use: 20 mg/kg bodyweight (1 ml/15 kg) to be administered by intramuscular injection twice 48 hours apart using a 16 gauge needle.
Subcutaneous use: 40 mg/kg bodyweight (2 ml/15 kg) to be administered once only using a 16 gauge needle.

Sheep:
Intramuscular use: 20 mg /kg bodyweight (1 ml/15 kg bodyweight) to be administered daily for three consecutive days.
Pharmacokinetic studies showed that mean plasma concentrations remain above MIC_{90} (1 µg/ml) for up to 18 hours after administration of the product at the recommended treatment dose. The pre-clinical data provided supported the recommended treatment interval (24 hours) for target pathogens with MIC up to 1 µg/ml.

For metaphylaxis
Cattle:
Subcutaneous use: 40 mg/kg bodyweight (2ml/15kg) to be administered once only 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 cattle and 4 ml for sheep.
The injection should only be given in the neck.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

Swab septum before removing each dose. Use a dry sterile needle and syringe.
The vials should not be broached more than 20 times. User should therefore select the most appropriate vial size according to the target species to be treated.
When treating groups of animals at the same time, use of a draw-off needle in the vial stopper is recommended to avoid excess stopper broaching. The draw-off needle should be removed after treatment.

10. Withdrawal periods

Meat and offal:

Cattle:	IM (20 mg/kg bodyweight, twice):	30 days.
	SC (40 mg/kg bodyweight, once):	44 days.
Sheep:		39 days.

Milk:
Not authorised for use in animals producing milk for human consumption including pregnant animals intended to produce milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Do not refrigerate.
Protect from frost.

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

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 aquatic organisms.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Vm 06376/5053

Pack sizes: 50, 100 and 250 ml vials.
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:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
TriRx Segré
La Grindolière
Zone Artisanale
Segré
49500 Segré-en-Anjou Bleu
France

Contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V Veterinary medicinal product subject to prescription.

Approved 11 June 2025
Gavin Hall