SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Florfenicol 300 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
N-methyl-2-pyrollidone	250 mg
Propylene glycol	
Macrogol 300	

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

3. CLINICAL INFORMATION

3.1 Target species

Cattle and sheep.

3.2 Indications for use for each target species

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 infections due to *Mannheimia haemolytica* and *Pasteurella multocida* susceptible to florfenicol.

3.3 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.

3.4 Special warnings

None.

3.5 Special precautions for use

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 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 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.

[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 fetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

Swab septum before removing each dose. Use a dry sterile needle and syringe.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.
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.

For treatment

Cattle:
Intramuscular use: 20 mg/kg bodyweight (1 ml/15 kg) to be administered 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. The dose volume given at any one injection site should not exceed 10 ml.
The injection should only be given in the neck.

Sheep:
Intramuscular use: 20 mg florfenicol/kg bodyweight (1 ml/15 kg) to be administered daily for three consecutive days. The volume administered per injection site should not exceed 4 ml.

Pharmacokinetic studies showed that mean plasma concentrations remain above MIC_{90} (1 µg/ml) for up to 18 hours after administration of the veterinary medicinal product at the recommended treatment dose. The pre-clinical data 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 (2 ml/15 kg) to be administered once only using a 16 gauge needle. The dose volume given at any one injection site should not exceed 10 ml.
The injection should only be given in the neck.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Cattle:
No symptoms other than those described in section 3.6.

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01BA90.

4.2 Pharmacodynamics

Florfenicol is a synthetic broad spectrum antibiotic effective against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at the ribosomal level and is bacteriostatic. Laboratory tests have shown that florfenicol is active against the most commonly isolated bacterial pathogens involved in ovine and bovine respiratory disease which include *Mannheimia haemolytica, Pasteurella multocida,* and for cattle *Histophilus somni.*

Florfenicol is considered to be a bacteriostatic agent, but *in vitro* studies of florfenicol demonstrate bactericidal activity against *Mannheimia haemolytica, Pasteurella multocida* and *Histophilus somni*.

MIC data for the target pathogens are presented in the table below:

Species	**Range (µg/ml)**	**MIC_{50} (µg/ml)**	**MIC_{90} (µg/ml)**
Mannheimia haemolytica (n=151)	0.25 - 2	1	1
Pasteurella multocida (n=88)	0.25 - 0.5	0.5	0.5

Strains were isolated from sheep suffering from respiratory tract infection in Germany, United Kingdom, Spain and France between 2006 and 2010.

4.3 Pharmacokinetics

Cattle:
Intramuscular administration at the recommended dose of 20 mg/kg maintains efficacious blood levels in cattle for 48 hours. Maximum mean serum concentration (C_{max}) of 3.37 µg/ml occurs at 3.3 hours (t_{max}) after dosing. The mean serum concentration 24 hours after dosing was 0.77 µg/ml.

Subcutaneous administration at the recommended dose of 40 mg/kg maintains efficacious blood levels in cattle (ie above the MIC_{90} of the main respiratory pathogens) for 63 hours. Maximum serum concentration (C_{max}) of approximately 5 µg/ml occurs approximately 5.3 hours (t_{max}) after dosing. The mean serum concentration 24 hours after dosing is approximately 2 µg/ml.

The harmonic mean elimination half-life was 18.3 hours.

Sheep:
After initial intramuscular administration of florfenicol (20 mg/kg), the mean maximum serum concentration of 10.0 µg/ml is reached after 1 hour. Following the third intramuscular administration, the maximum serum concentration of 11.3 µg/ml is reached after 1.5 hours. The elimination half-life was estimated to be 13.76 + 6.42h. Bioavailability is about 90 %.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

50, 100 and 250 ml colourless Type I glass vials closed with bromobutyl rubber stoppers with aluminium seals.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for aquatic organisms.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/5053

8. DATE OF FIRST AUTHORISATION

25 February 2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

June 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 11 June 2025

Gavin Hall