1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR Swine 300 mg/mL Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:

Florfenicol 300.00 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-methylpyrrolidone	250 mg
Propylene glycol	
Macrogol 300	

Clear, light yellow to straw-colored, somewhat viscous solution, free from foreign matter.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not administer to boars intended for breeding. See section 3.7.
Do not administer in cases of previous allergic reactions to florfenicol.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in piglets of less than 2 kg.

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.

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

Do not use the veterinary medicinal product in known cases of sensitivity to propylene glycol and polyethylene glycols.
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.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Common (1 to 10 animals / 100 animals treated):	Diarrhoea[1]; Perianal inflammation[1], Rectal oedema[1]; Pyrexia[2], Depression[2]; Dyspnoea[2];
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[3], Injection site lesion[4], Injection site inflammation[4].

[1] Can be observed for one week in 50% of the animals.
[2] Under field conditions in approximately 30% of treated pigs a week or more after administration of the second dose.
[3] Lasting up to 5 days.
[4] May be seen up to 28 days.

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 pigs 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.
Do not use the product during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramuscular use.
15 mg/kg bodyweight (1 mL per 20 kg) by intramuscular use into the neck muscle twice at 48 hour intervals using a 16-gauge needle.
The volume administered per injection site should not exceed 3 mL.
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 accuracy as possible to avoid underdosing.

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

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.

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: 18 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ01BA90

4.2 Pharmacodynamics

Florfenicol is a broad-spectrum synthetic antibiotic active against most Gram-positive and Gram-negative bacteria isolated from domestic animals. Florfenicol acts by inhibition of protein synthesis at the ribosomal level and is bacteriostatic. However, bactericidal activity has been demonstrated *in vitro* against *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

In vitro testing has shown that florfenicol is active against the bacterial pathogens most commonly isolated in respiratory diseases in pigs, including *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*.

4.3 Pharmacokinetics

In pigs intravenously administered florfenicol had a mean plasma clearance rate of 5.2 mL/min/kg and a mean volume of distribution at equilibrium of 948 mL/kg. The mean terminal half-life is 2.2 hours.

After initial intramuscular administration of florfenicol, maximum serum concentrations of between 3.8 and 13.6 μg/mL are reached after 1.4 hours and the concentrations deplete with a terminal mean half-life of 3.6 hours. After a second intramuscular administration, maximum serum concentrations of between 3.7 and 3.8 μg/mL are reached after 1.8 hours. Serum concentrations drop below 1 μg/mL, the MIC_{90} for the target porcine pathogens, 12 to 24 hours following IM administration. Florfenicol concentrations achieved in lung tissue reflect plasma concentrations, with a lung:plasma concentration ratio of approximately 1.

After administration to pigs by the intramuscular route, florfenicol is rapidly excreted, primarily in urine. The florfenicol is extensively metabolised.

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.
Discard unused material.

5.4 Nature and composition of immediate packaging

Colourless Type I glass vials closed with Grey bromobutyl rubber stoppers with aluminium seals, in a cardboard box.
Cardboard box containing 1 vial of 20 ml, 50 ml, 100 ml, 250 ml and 500 ml.

Not all pack sizes may be marketed.

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

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

The veterinary medicinal product should not enter water courses as florfenicol may be dangerous for 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/241/001

8. DATE OF FIRST AUTHORISATION

21/03/2003

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

22/11/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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