1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR Swine 300 mg/mL Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each mL contains:
Florfenicol 300.00 mg

Excipient(s):
N-Methyl-2-Pyrrolidone 250.00 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, light yellow to straw-colored, somewhat viscous solution, free from foreign matter

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not administer to boars intended for breeding.
Do not administer in cases of previous allergic reactions to florfenicol.
See section 4.7.

4.4 Special warnings

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not use in piglets of less than 2 kg.
The 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 product in known cases of sensitivity to propylene glycol and polyethylene glycols.
Care should be taken to avoid accidental self-injection.

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.

4.6 Adverse reactions (frequency and seriousness)

Commonly observed adverse effects are transient diarrhoea and/or peri-anal and rectal erythema/oedema which may affect 50% of the animals. These effects can be observed for one week. Under field conditions approximately 30% of treated pigs presented with pyrexia (40°C) associated with either moderate depression or moderate dyspnea a week or more after administration of the second dose.

Transient swelling lasting up to 5 days may be observed at the site of injection. Inflammatory lesions at the injection site may be seen up to 28 days.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

15 mg/kg bodyweight (1 mL per 20 kg) by intramuscular injection 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal*: 18 days

* The withdrawal period is calculated from the last administration of the drug. It should be noted that whatever the withdrawal period no food of animal origin can be given to humans during the period of treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use (Amphenicols)
ATC Vet Code: QJ01BA90

5.1 Pharmacodynamic properties

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*.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N-Methyl-2-Pyrrolidone
Propylene Glycol
Macrogol 300 (polyethylene glycol 300)

6.2 Incompatibilities

Do not mix the product with other medicinal products.

6.3 Shelf life

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

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Pack Sizes
20, 50, 100, 250 and 500 mL colourless Type I glass vials closed with Grey bromobutyl rubber stoppers with aluminium seals.

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited

8. MARKETING AUTHORISATION NUMBER(S)

VPA10996/241/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 March 2003

10 DATE OF REVISION OF THE TEXT

29 November 2023