Nuflor®
FLORFENICOL

Swine Injectable Solution 300 mg/ml

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Product Registration holder:
Intervet (M) Sdn. Bhd.,
B-22-1 & B-22-2, The Ascent Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor Darul Ehsan, Malaysia

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR Florfenicol Swine Injectable Solution 300 mg/ml

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:
300 mg Florfenicol
150 mg Propylene glycol
250 mg N-methyl-2-pyrrolidone

4. PRODUCT DESCRIPTION

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

5. INDICATIONS

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

6. CONTRAINDICATIONS

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

7. ADVERSE REACTIONS

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.

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

8. TARGET SPECIES

Pigs.

9. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

15 mg/kg body weight (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.

10. ADVICE ON CORRECT ADMINISTRATION

Wipe the stopper before removing each dose. Use a dry, sterile syringe and needle. Do not broach the vial more than 25 times.

11. WITHDRAWAL PERIOD

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.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of reach and sight of children.
Do not store above 25ºC.
Do not refrigerate.
Protect from frost.
Do not use after the expiry date stated on the label.

13. SHELF LIFE AFTER FIRST OPENING THE CONTAINER

28 days.

14. SPECIAL WARNINGS

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.

Under field conditions approximately 30% of treated pigs presented with pyrexia (40ºC) associated with either moderate depression or moderate dyspnea a week or more after administration of the second dose. Care should be taken to avoid accidental self-injection.

Do not use in known cases of sensitivity to propylene glycol and polyethylene glycols.

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.

15. PEGNANCY AND LACTATION

Studies in laboratory animals have not revealed any evidence of embryo- or foeto-toxic potential for florfenicol. However, the safety of the product in sows during pregnancy and lactation has not been demonstrated.

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.

Use of the product during pregnancy and lactation is not therefore recommended.

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Medicines should not be disposed of via wastewater or household waste. Any unused product or waste material should be disposed of in accordance with national requirements.

17. SYMPTOMS AND TREATMENT OF 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.

18. INTERACTION WITH OTHER MEDICINES

None known.

19. INCOMPATIBILITES

Not to mix the product with other medicinal products.

20. OTHER INFORMATION

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 ribosmol level and is bacteriostatic. However, bactericidal activity has been demonstrated *in vitro* against *Actinobacillus plueuropneumoniae* 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*.

In pigs intravenously administered florfenicol had a mean plasma clearance rate of 5.2 ml/min/kg and a mean volume 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 the 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 tissues 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.

21. MAXIMAL RESIDUAL LIMIT

Animal Species	MRLs	Target Tissues	Other provisions
Porcine	300 µg/kg	Muscle	
	500 µg/kg	Skin + Fat	
	2000 µg/kg	Liver	
	500 µg/kg	Kidney	

22. PRESENTATION

100ml colourless type I glass vial.

23. DATE OF REVISION

7th March 2025.

MSD
Animal Health