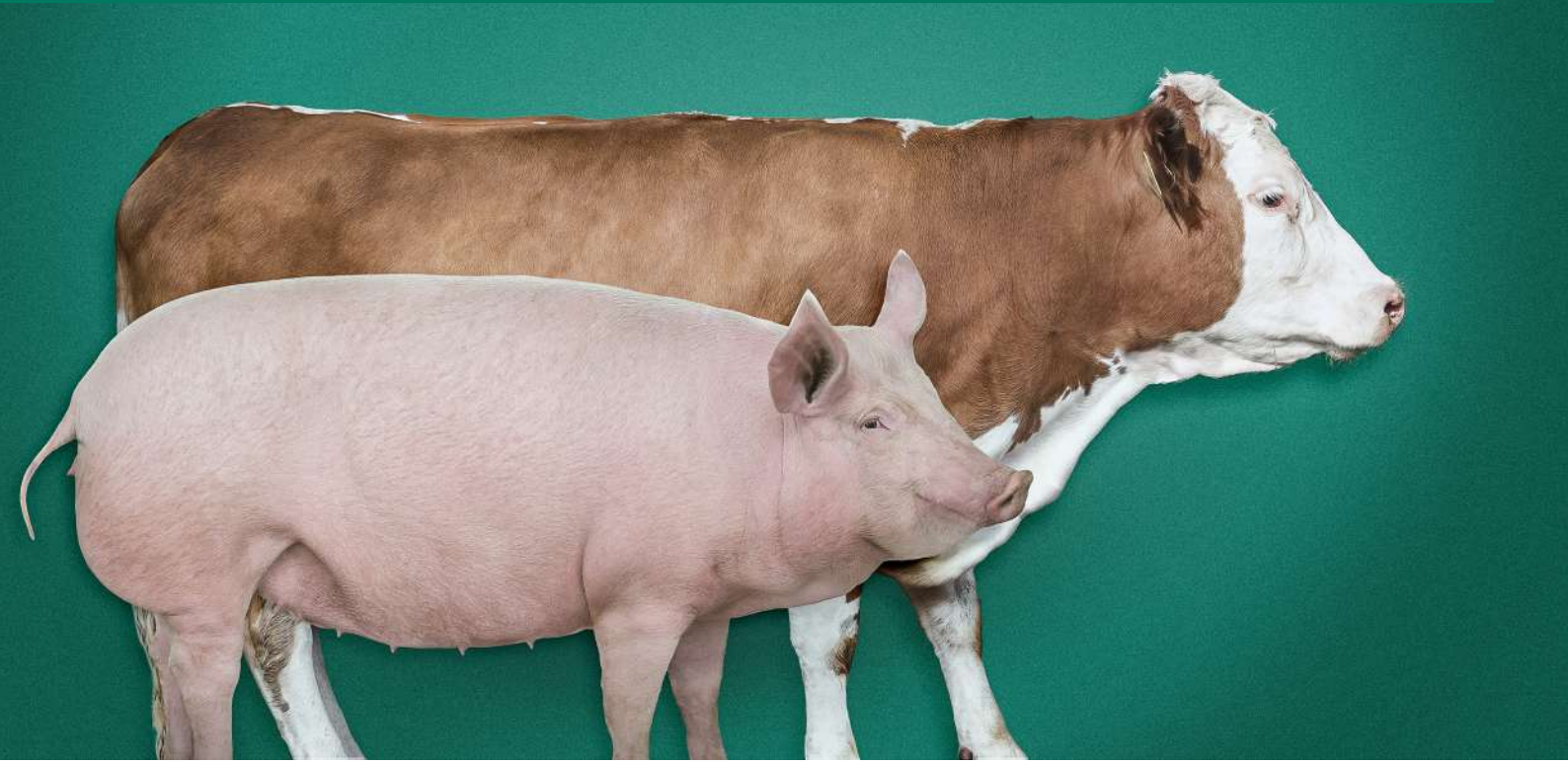
NIFENCOL

300MG/ML SOLUTION FOR INJECTION

Florfenicol 300mg/ml

DATA SHEET



INDICATIONS

• **Cattle:** Metaphylaxis and treatment of respiratory tract infections in cattle due to *Histophilus somni*, *Mannheimia haemolytica* and *Pasteurella multocida*, susceptible to florfenicol.

The presence of the disease in the herd should be established before treatment.

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

BENEFITS

- **Cattle- intramuscular or subcutaneous injection**
- **Pigs- intramuscular injection**

LIST No	UNIT PACKAGE	CASE SIZE
1NIF001	100ml	70

See reverse for Administration & Dosage

Nifencol®

300mg/ml Solution for Injection for Cattle and Pigs

Florfenicol 300mg/ml

PRESENTATION
A clear slightly yellowish solution for injection.
Each ml contains 300mg florfenicol.

TARGET SPECIES
Cattle and Pigs.

INDICATIONS FOR USE
Cattle:
Metaphylaxis and treatment of respiratory tract infections in cattle due to *Histophilus somni*,. *Mannheimia haemolytica* and *Pasteurella multocida*, susceptible to florfenicol.
The presence of the disease in the herd should be established before treatment.
Pigs:
Treatment of acute outbreaks of respiratory disease caused by strains of *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* susceptible to florfenicol.

SPECIAL PRECAUTIONS FOR USE
Do not administer to adult bulls and boars intend for breeding purposes.
Do not use in case of hypersensitivity or previous allergic reactions to florfenicol or to any of the excipients.
This veterinary medicinal product does not contain an antimicrobial preservative.
i) Special precautions for use in animals
Do not administer to piglets of less than 2 kg. The veterinary medicinal product should be used in conjunction with susceptibility testing and take into account official and local antimicrobial policies.
ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
Take care to avoid accidental self-injection. In case of accidental self-injection, seek medical advice taking the label or package leaflet with you to show the physician. Avoid skin or eye contact with the product.
In case of contact with the skin or eyes, rinse the affected area immediately with plenty of water. Wash hands after use. People with known hypersensitivity to propylene glycol or polyethylene glycols should avoid contact with the veterinary medicinal product.

ADVERSE REACTIONS (FREQUENCY & SERIOUSNESS)
In cattle, a decrease in food consumption and transient softening of the faeces may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.
Administration of the product by the intramuscular and subcutaneous routes may cause inflammatory lesions at injection site which persist for 14 days. On very rare occasions, anaphylactic reactions have been reported in cattle.
In pigs, 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 dyspnoea 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.

USE DURING PREGNANCY AND LACTATION
Studies in laboratory animals have produced no evidence of teratogenic or foetotoxic effects.

Cattle:
The safety of the veterinary medicinal product has not been established during pregnancy. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.
Pig:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. It is not recommended to use the veterinary medicinal product in pigs during pregnancy and lactation.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
None known.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE
Cattle: Intramuscular or subcutaneous injection. Pig: intramuscular injection.

Cattle:
Treatment: IM route: 20 mg florfenicol /kg bodyweight (1ml of the product/15kg) to be administered twice 48 hours apart using a 16 gauge needle.
SC route: 40 mg florfenicol /kg bodyweight (2ml of the product/15kg) to be administered once only using a 16 gauge needle.
Metaphylaxis: SC route: 40 mg florfenicol/kg bodyweight (2ml of the product/15kg) to be administered once only using a 16 gauge needle.
Pigs:
15 mg florfenicol/kg bodyweight (1 ml of the product / 20 kg) by intramuscular injection twice at 48 hour intervals using a 16-gauge needle. The dose volume given at any one injection site should not exceed 10ml for both routes of administration (intramuscular and subcutaneous) in cattle and 3 ml in pigs. The injection should only be given in the neck in both target species.
To ensure a correct dosage body weight of the animals should be determined as accurately as possible to avoid underdosing.
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 or if relapse occurs, treatment should be changed using another formulation or another antibiotic and continued until clinical signs have resolved.
Swab septum before removing each dose. Use a dry sterile needle and syringe.
Do not broach the stopper of vial more than 25 times.

OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES)
In swine, after administration of 3 times the recommended dose, a reduction in feeding, hydration and weight gain has been observed. After administration of 5 times the recommended dose, vomiting has also been noted.

WITHDRAWAL PERIODS
Cattle:
Meat and offal: by IM (at 20 mg/kg bodyweight, twice): 30 days by SC (at 40 mg/kg bodyweight, once): 44 days
Milk: Not authorised for use in cattle producing milk for human consumption, including during the dry period. **Pigs:** meat and offal 18 days

PHARMACODYNAMIC PROPERTIES
Florfenicol is a synthetic broad spectrum antibiotic effective against most Gram-positive and Gram-negative isolated from domestic animals. Florfenicol acts by inhibiting protein synthesis at ribosomal level and is bacteriostatic.
Mechanisms of resistance to florfenicol include specific and non-specific drugs transporters and RNA methyltransferases. Co-resistance with the third-generation cephalosporins has been observed in respiratory and digestive *E. coli*. In cattle, 99% of *P. multocida* isolates (n=156) and 98% of *M. haemolytica* isolates (n=109) were susceptible to florfenicol (strains isolated in France in 2012). In pigs, 99% of *A. pleuropneumoniae* isolates (n=159) and 99% *P. multocida* isolates (n=150) were susceptible to florfenicol (strains isolated in France in 2012).

PHARMACOKINETIC PROPERTIES
In cattle, IM administration at 20mg/kg maintains efficacious blood levels in cattle for 48 hours. C_{max} of 3.37µg/ml occurs at 3.3 hours (T_{max}) after dosing.
The mean plasma concentration 24 hours after dosing was 0.77µg/mL. SC administration at 40mg/kg maintains blood levels above the MIC_{90} of the main respiratory pathogens for 63 hours. C_{max} ~ 5 µg/ml occurs approximately 5.3 hours (T_{max}) after dosing. The mean plasma concentration 24 hours after dosing is approximately 2 µg/ml. Elimination half-life = 18.3 hours.

In pigs: after initial IM administration of 15mg/kg C_{max} =3.8-13.6 mg/ml reached after 1.4 hours Terminal mean half-life = 3.6 hours. After second IM administration, C_{max} = 3.7-3.8 mg/ml reached after 1.8 hours. Plasma concentrations drop below 1 mg/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. Florfenicol is rapidly excreted, primarily in urine And extensively metabolised.

LIST OF EXCIPIENTS
N-methylpyrrolidone
Propylene glycol
Macrogol 300

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

SHELF-LIFE
Shelf-life as packaged for sale: 2 years.
Shelf life after first use: 28 days.

SPECIAL PRECAUTIONS FOR STORAGE
Keep the vial in the outer carton in order to protect from light.

NATURE AND COMPOSITION OF IMMEDIATE PACKAGING
Polypropylene vial of 100 ml and 250 ml, closed with bromobutyl stopper secured with flip-off aluminium collar. One vial of 100 ml or 250 ml is available in a cardboard box. Not all pack sizes may be marketed.

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 products should be disposed of in accordance with local requirements.

LEGAL CATEGORY
POM-V

MARKETING AUTHORISATION NUMBER
VM 32509/4011

DISTRIBUTED BY
Bimeda UK
Unit 2, Bryn Cefni Industrial Park
Llangefni, Anglesey,
Wales, LL777XA
Tel: +44 (0) 1248 725 400

Use Medicines Responsibly.
Noah.co.uk/responsible

A full product SPC is available on request from Bimeda or alternatively can be found on the VMD website.

TAKE TIME  OBSERVE LABEL DIRECTIONS

www.bimeda.co.uk

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