Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLORGOLD 300 mg/ml solution for injection for cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Florfenicol	300.0 mg

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, light yellow to straw coloured liquid

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

In cattle:
Treatment of respiratory disease caused by strains of *Histophilus somni, Mannheimia haemolytica and Pasteurella multocida* susceptible to florfenicol.

4.3 Contraindications

Do not use in adult bulls intended for breeding purposes.
Do not administer in cases of previous allergic reactions to florfenicol.
Do not use in the case of known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

Do not exceed the recommended treatment dose or the recommended duration of treatment.

4.5 Special precautions for use

Special precautions for use in animals

Whenever possible, the product should only be used based on susceptibility testing. Official, national and regional antimicrobial policies should be taken into account when the product is used.
The safety and efficacy of the veterinary medicinal product has not been established after intravenous use.

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

Care should be taken to avoid accidental self-injection. In case of self-injection, seek medical advice immediately and show the package leaflet or the label to 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. If accidental ingestion occurs, rinse the mouth with plenty of water and seek medical advice immediately. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

A decrease in food consumption may occur during the treatment period. The treated animals recover quickly and completely upon termination of treatment.

Administration of the product by subcutaneous injection may induce a transient local swelling in the subcutaneous and underlying muscle tissue lasting up to 42 days. Inflammatory lesions within the subcutis and underlying muscle surface were observed up to 56 post treatment.

In very rare cases, anaphylactic shocks have been reported in bovines.

4.7 Use during pregnancy, lactation or lay

The effect of florfenicol on bovine reproductive performance and pregnancy has not been assessed. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Subcutaneous route: 40 mg/kg body weight (2ml/15kg) to be administered once only using a 16 gauge needle. The dose volume given at any one injection site should not exceed 15ml.

The injection should only be given in the neck.

Swab septum before removing each dose. Use a dry sterile needle and syringe.
Do not broach the vial more than 10 times.

To ensure a correct dosage the body weight should be determined as accurately as possible to avoid underdosing.

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

After administration of 3-fold and 5-fold the recommended dose and 3-fold the recommended duration of treatment, a decrease in food and water consumption has been observed.

4.11 Withdrawal Period(s)

Meat and offal: 75 days
Milk: Not authorised for use in lactating animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use
ATCVet code: QJ01BA90

5.1 Pharmacodynamic properties

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 acts time-dependently and is active against the most commonly isolated bacterial pathogens involved in bovine respiratory disease which include *Histophilus somni*, *Mannheimia haemolytica* and *Pasteurella multocida*, .

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

The only mechanisms of chloramphenicol resistance that are known to have significant clinical relevance are CAT-mediated inactivation and efflux-pump resistance. Of these, only some of the efflux mediated resistance would also confer resistance to florfenicol and thus have the potential to be affected by florfenicol use in animals.

Using CLSI breakpoints (≤2 µg/ml: susceptible; 2-4 µg/ml: intermediate; ≥8 µg/ml: resistant) all target pathogens tested are susceptible.
MIC data for the recent target pathogens (2009-2012) are presented in the table below:

Bacterial species (number of isolates)	MIC range (µg/ml)	MIC_{50} (µg/ml)	MIC_{90} (µg/ml)	%R (MIC>4 µg/ml)[a]
Mannheimia haemolytica (149)	0.5 - 4	1	1	0.0
Pasteurella multocida (134)	0.25 - 2	0.5	0.5	0.0
Histophilus somni (66)	0.12- 0.25	0.25	0.25	0.0

[a]: CLSI M31-A3

5.2 Pharmacokinetic properties

In cattle, after subcutaneous administration of the veterinary medicinal product at the recommended dose of 40 mg/kg, the mean maximum serum concentration (C_{max}) of 5.93 µg/ml is reached in 4 hours (T_{max}) after administration.
The mean serum concentration 24 hours post administration is 2 µg/ml
The terminal half-life is approximately 35 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pyrrolidone
Triacetin

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first broaching the immediate packaging: 28 days

6.4 Special precautions for storage

Protect from frost.

6.5 Nature and composition of immediate packaging

Pack Sizes
100, 250 and 500 ml colourless Type I glass vials closed with bromobutyl rubber stoppers with aluminium seals (20 or 32 mm).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.,
Magna Drive,
Magna Business Park,
Citywest Road,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/270/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19th July 2013

10 DATE OF REVISION OF THE TEXT