Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLOR 300 mg/ml solution for injection for cattle.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains	
Active substance:	
Florfenicol	300.00 mg
Excipients:	

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

Cattle.

4.2 Indications for use, specifying the target species

Diseases caused by florfenicol susceptible bacteria.
Preventive and therapeutic treatment of respiratory tract infections in cattle due to *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni.* The presence of the disease in the herd should be established before preventive treatment.

4.3 Contraindications

Do not use in adult bulls intended for breeding purposes.
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

None.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not revealed any evidence of embryo- or foetotoxic potential for florfenicol. However, 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

Not investigated.

4.9 Amounts to be administered and administration route

For treatment
IM route: 20 mg/kg bodyweight (1ml/15kg) to be administered twice 48 hours apart using a 16 gauge needle.
SC route: 40 mg/kg bodyweight (2ml/15kg) to be administered once only using a 16 gauge needle. The dose volume given at any one injection site should not exceed 10mL.
The injection should only be given in the neck.

For prevention
SC route: 40 mg/kg bodyweight (2ml/15kg) to be administered once only using a 16 gauge needle. The dose volume given at any one injection site should not exceed 10mL.
The injection should only be given in the neck.

Swab septum before removing each dose. Use a dry sterile needle and syringe.
For 500 ml vials, do not breach the vial more than 25 times.

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

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

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.

4.11 Withdrawal Period(s)

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 permitted for use in lactating animals producing milk for human consumption.

* 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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterial for systemic use (Amphenicols)
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 is active against the most commonly isolated bacterial pathogens involved in bovine respiratory disease which include *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni* and *Arcanobacterium pyogenes.*

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

5.2 Pharmacokinetic properties

Intramuscular administration at the recommended dose of 20mg/kg maintains efficacious blood levels in cattle for 48 hours. Maximum mean serum concentration (Cmax) of 3.37µg/ml occurs at 3.3 hours (Tmax) after dosing.
The mean serum concentration 24 hours after dosing was 0.77µg/mL.

The administration of the product by subcutaneous route at the recommended dosage of 40mg/kg maintains bovine efficacious blood levels in cattle (ie above the MIC_{90} of the main respiratory pathogens) for 63 hours. Maximum serum concentration (Cmax) of approximately 5 µg/ml occurs approximately 5.3 hours (Tmax) after dosing. The mean serum concentration 24 hours after dosing is approximately 2 µg/ml.

The harmonic mean elimination half life was 18.3 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N-methyl-2-pyrollidone
Propylene glycol
Macrogol 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 packagaing: 28 days

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

20, 50, 100, 250 and 500 mL colourless Type I glass vials closed with bromobutyl rubber stoppers with aluminium seals.
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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Ltd.,
Shire Park,
Welwyn Garden City,
Hertfordshire,
AL7 1TW,
England.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/011/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11th June 2010

10 DATE OF REVISION OF THE TEXT