ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND IMMEDIATE PACKAGE

{100 ml, 250 ml, 500 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLORGOLD 300 mg/ml solution for injection for cattle
Florfenicol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
300 mg Florfenicol

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml
500 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous administration
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first broachingthe immediate packaging: 28 days
Once opened, use by: _____

11. SPECIAL STORAGE CONDITIONS

Protect from frost.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4605

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

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

Marketing authorisation holder:
Intervet UK Ltd
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Manufacturer responsible for batch release:
Vet Pharma Friesoythe
Sedelsberger Strasse 2-4
26169 Friesoythe
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NUFLORGOLD 300 mg/ml Solution for Injection for Cattle
ES: NUFLOR SC 300 mg/ml solución inyectable para bovino
Florfenicol

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

NUFLORGOLD is a clear, light yellow to straw coloured liquid solution for injection containing 300 mg Florfenicol per ml.

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

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 days post treatment.

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

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

7. TARGET SPECIES

Cattle.

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

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 15 ml.

The injection should only be given in the neck.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Protect from frost.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after "EXP
Shelf-life after first broachingthe container: 28 days.

12. SPECIAL WARNINGS

Special warnings for each target species:
Do not exceed the recommended treatment dose or the recommended duration of treatment.

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 veterinary 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.

Pregnancy:
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.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.