ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LDPE/HDPE/paper sealed bag containing 5 kg premix
LDPE/paper/paper/paper sealed bag containing 25 kg premix

Note: for the product there is no carton box and no package leaflet.
All information is conveyed to the label.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nuflor 40 mg/g Premix for Medicated Feeding Stuff for Swine
Florfenicol

2. STATEMENT OF ACTIVE SUBSTANCES

Composition per gram:

Active substance:

Florfenicol	40 mg

Excipients:

Propylene Glycol (E 1520)	10 mg
Ground Limestone	qs to 1g

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff
White to off-white, free flowing powder with red and/or black grains dispersed throughout.

4. PACKAGE SIZE

5 kg
25 kg

5. TARGET SPECIES

Pigs (Fattening pigs)

6. INDICATION(S)

For the treatment and metaphylaxis of swine respiratory disease caused by *Pasteurella multocida* susceptible to florfenicol in infected herds. The presence of the disease in the herd must be established before the product is used.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

To be administered orally, in medicated feeding stuff.

Dosage:
10 mg of florfenicol per kg body weight (bw) (equivalent to 250 mg product) per day administered for 5 consecutive days.

Administration:
For a daily feed intake of 50 g/kg body weight, this dosage corresponds to a rate of incorporation of 5 kg of premix per ton of feed, i.e. 200 ppm of florfenicol.
The rate of incorporation of the medicated premix in the feed may be increased in order to achieve the required dosage on an mg/kg body weight basis and to take into account the actual feed intake. Thus, the inclusion level may need adjusting as follows to give the correct dose.

$$\frac{\text{250 mg product per kg body weight and day} \times \text{Average pig body weight (kg)}}{\text{Average daily feed intake (kg/animal)}} = \text{mg product per kg of feed}$$

The maximum rate of incorporation is 12.5 kg/ton (500 ppm of florfenicol), higher rates of inclusion may lead to poor palatability and decreased food consumption. Under no circumstances should the incorporation rate of the premix be below 5 kg/ton of feed.

In all cases the recommended dose of 10 mg of florfenicol per kg of body weight per day, for 5 consecutive days has to be respected.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing. The required dose should be measured by suitably calibrated weighing equipment.

A horizontal ribbon mixer should be used to incorporate the product into the feeding stuff. It is recommended that the product is added to the mixer containing the feeding stuff ingredients and mixed thoroughly to produce a homogeneous medicated feeding stuff. Medicated feed may also then be pelleted. Pelleting conditions include a pre-conditioning step with steam and then the mixture is passed through a pelleter or extruder under normal conditions.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 14 days

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications
Do not administer to boars intended for breeding.
Do not use in case of hypersensitivity to the active substance or any of the excipients.

Special warnings for each target species:
Animals showing a decreased appetite and/or a poor general condition should be treated by the parenteral route.

Special precautions for use in animals:
The product should be used in conjunction with susceptibility testing and take into account official and local policy relating to the use of antimicrobials.
This premix is intended for the manufacturing of solid medicated feed and cannot be used as is; the incorporation rate of the premix in feed cannot be lower than 5 kg/ton.
This premix contains ground limestone, which can lead to a decrease in food consumption and to a phosphorus calcium imbalance in feed intake. Care should therefore be taken to consider the calcium content of the final medicated feed.
Treatment should not exceed 5 days.
In a field clinical study, within a week after the administration of the last dose, the incidence of pigs presenting either mild depression and/or mild dyspnoea and/or pyrexia (40°C) was approx. 20 % in the initially severely ill animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Skin sensitisation may occur. Avoid skin contact.
Do not handle this product in case of known sensitisation to active substance or any of the excipients.
Handle this product with care to avoid exposure during incorporation of premix into feed and administration of feed to animals, taking all recommended precautions.
Wear either a disposable half-mask respirator conforming to European standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143, chemically resistant gloves, protective coveralls and goggles while incorporating the premix into feed.
Wear gloves and do not smoke, eat, or drink when handling the product or medicated feed.
Wash hands thoroughly with soap and water after use of the product or medicated feed. Rinse thoroughly with water in case of exposure.
If you develop symptoms following exposure such as skin rash, you should seek medical advice and take the package leaflet or the label with you.

Other precautions:
Manure from treated swine must be stored for a minimum of one month before being spread and incorporated in fields.

Adverse reactions:
Commonly observed adverse effects are diarrhoea, perianal inflammation and rectal eversion. Increased serum calcium may also be observed. These effects are transient, resolving on cessation of treatment.

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

Use during pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Therefore the use is not recommended during pregnancy and lactation.

Overdose:
In the event of overdose, a reduction in food and water consumption, together with a decrease in body weight may be observed. There may be an increase in refused feed and an increase in serum calcium.

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

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

This veterinary medicinal product does not require any special storage conditions.
Shelf life after incorporation into meal or pelleted feed: 3 months.
Once opened, use within 28 days.

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

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

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

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturers for the batch release:

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

Intervet Productions S.R.L.
Via Nettunense Km 20, 300
04011 Aprilia (LT)
Italy

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4575

17. MANUFACTURER'S BATCH NUMBER

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

Other information
LDPE/HDPE/paper sealed bag containing 5 kg premix.
LDPE/paper/paper/paper sealed bag containing 25 kg premix
Not all pack sizes maybe marketed.