ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

LDPE sealed bag containing 5 kg
LDPE sealed bag containing 25 kg

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nuflor 40 mg/g Premix for Medicated Feeding Stuff for Pigs

2. COMPOSITION

Each gram contains:

Active substance:
Florfenicol 40 mg

Excipients:
Propylene glycol (E1520) 10 mg
Ground limestone qs to 1 g

White to off-white, free flowing powder with red and/or black grains dispersed throughout.

3. PACKAGE SIZE

5 kg
25 kg

4. TARGET SPECIES

Pigs (for fattening).

5. INDICATIONS FOR USE

Indications for use

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 veterinary medicinal product is used.

6. CONTRAINDICATIONS

Contraindications

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

7. SPECIAL WARNINGS

Special warnings

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

Special precautions for safe use in the target species:
The veterinary medicinal product should be used in conjunction with susceptibility testing and take into account official and local policy relating to the use of antimicrobials.
This veterinary medicinal product is intended for the manufacturing of solid medicated feed and cannot be used as is the incorporation rate of the veterinary medicinal product in feed cannot be lower than 5 kg/ton.
This veterinary medicinal product 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 approximately 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.
People with known hypersensitivity to florfenicol or any of the excipients should avoid contact with the veterinary medicinal product. Handle this veterinary medicinal product with care to avoid exposure during incorporation of veterinary medicinal product 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 veterinary medicinal product into feed.
Wear gloves and do not smoke, eat, or drink when handling the veterinary medicinal product or medicated feed.
Wash hands thoroughly with soap and water after use of the veterinary medicinal 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 show the package leaflet or the label to the physician.
Special precautions for the protection of the environment:
Manure from treated swine must be stored for a minimum of one month before being spread and incorporated in fields.

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.

8. ADVERSE EVENTS

Adverse events

Pigs (for fattening):

Common (1 to 10 animals / 100 animals treated):
Diarrhoea[1], Perianal inflammation[1], Rectal prolapse[1].
Undetermined frequency (cannot be estimated from available data):):
Hypercalcaemia[1]Hypercalcaemia (increased levels of calcium in the blood)[1].

[1]These effects are transient, resolving on cessation of treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details on this label, or via your national reporting system
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine.

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9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Oral use.

Dosage:
10 mg of florfenicol per kg body weight (equivalent to 250 mg veterinary medicinal 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 the veterinary medicinal product per ton of feed, i.e. 200 ppm of florfenicol.
The rate of incorporation of the veterinary medicinal product 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:

$$\frac{\text{250 mg veterinary medicinal product / kg body weight /day} \times \text{Average body weight (kg) of animals to be treated}}{\text{Average daily feed intake (kg/animal)}} = \text{mg veterinary medicinal product per kg of feed}$$

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 veterinary medicinal product be below 5 kg/ton of feed.

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 veterinary medicinal product into the feeding stuff. It is recommended that the veterinary medicinal 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.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration
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.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 14 days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes: 5 kg and 25 kg bags.

Not all pack sizes may be marketed.

Vm 01708/3042

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Manufacturers responsible for batch release:
Intervet Productions S.R.L.
Via Nettunense Km 20
300 04011, Aprilia (LT), Italy

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Local representatives <and contact details to report suspected adverse reactions>:

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder listed below.>

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 28 days.

Shelf life after incorporation into meal or pelleted feed: 3 months

21. BATCH NUMBER

Lot {number}

Gavin Hall
Approved: 27 October 2024