ANNEX III

LABELLING AND PACKAGE LEAFLET

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

BAG

1. Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder:

Kernfarm B.V.
De Corridor 14d
3621 ZB Breukelen
The Netherlands

Manufacturer responsible for batch release:

Laboratorios Calier, S.A.
C/ Barcelonès, 26 – El Ramassar
08520 Les Franqueses del Vallès (Barcelona)
Spain

2. Name of the veterinary medicinal product

Flubenmix 5%, 50 mg/g Premix for Medicated Feeding Stuff
Flubendazole

3. Statement of the active substance(s) and other ingredients

Each gram contains:

Active substance:
Flubendazole .....50 mg

4. Pharmaceutical form

Premix for medicated feeding stuff.

5. Package size

25 kg

6. Indication(s)

Pig**:** treatment of pig helminthiasis caused by:
Ascaris suum
Hyostrongylus rubidus
Oesophagostomum dentatum
Trichuris suis
Strongyloides ransomi
Metastrongylus apri

Chicken, turkey, goose, partridge, pheasant: treatment of helminthiasis caused by:
Capillaria obsignata
Ascaridia galli
Syngamus trachea
Heterakis gallinarum
Trichostrongylus tenuis
Amidostomum anseris

The presence of the disease in the group/flock must be established before the product is used.
The product is for the treatment of adult stages of the helminth species.

7. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

8. Adverse reactions

If you notice any side effects, even those not already listed in this package leaflet, please inform your veterinary surgeon.

9. Target species

Pigs, chickens, turkeys, geese, partridges and pheasants.

10. Dosage for each species, route(s) and method of administration

Administration in feed:

Pigs:
Breeding pigs: 30 ppm flubendazole (equivalent to 600 g premix/tonne feed), for 7 - 10 days.
This corresponds to 0.37 mg flubendazole/kg bw/day (for a standard food consumption of 2.5 kg/day in a 200 kg sow).

Piglets and weaner pigs: 30 ppm flubendazole (equivalent to 600 g premix/tonne feed), for 5 days for the treatment of ascariasis and for 10 days for the treatment of Trichuris spp. infestations. This corresponds to 1,2 mg flubendazole/kg bw/day (for a standard food consumption of 0.5 kg/day in a 12,5 kg piglet and 1,0 kg in 25 kg weaner pig).

Fattening pigs: 30 ppm flubendazole (equivalent to 600 g premix/tonne feed), for 5 days for the treatment of ascariasis and for 10 days for the treatment of Trichuris spp. infestations. This corresponds to 1,2 mg flubendazole/kg bw/day (for a standard food consumption of 2.0 kg/day in a 50 kg fattening pig).

Chickens: 30 ppm flubendazole (equivalent to 600 g premix/tonne feed), for 7 days. This corresponds to 4,0 mg flubendazole/kg bw/day (for a standard food consumption of 0.02 kg/day in a 0.15 kg chicken) and corresponds to 1,9 mg flubendazole/kg bw/day (for a standard food consumption of 0.2 kg/day in a 3.2 kg chicken or 0.115 kg/day in a 1.8 kg chicken).

Turkeys: 20 ppm flubendazole (equivalent to 400 g premix/tonne feed), for 7 days.

This corresponds to 0,56 mg flubendazole/kg bw/day (for a standard food consumption of 0.63 kg/day in a 22.5 kg turkey) and corresponds to 2,35 mg flubendazole/kg bw/day (for a standard food consumption of 0.045 kg/day in a 0.38 kg turkey).

Geese: 30 ppm flubendazole (equivalent to 600 g premix/tonne feed), for 7 days.
This corresponds to 2,0 mg flubendazole/kg bw/day (for a standard food consumption of 0.55 kg/day in a 8 kg goose).

Pheasants: 60 ppm flubendazole (equivalent to 1200 g premix/tonne feed), for 7 days.
This corresponds to 2,7 mg flubendazole/kg bw/day (for a standard food consumption of 0.045 kg/day in a 1 kg pheasant).

Partridges: 60 ppm flubendazole (equivalent to 1200 g premix/tonne feed), for 7 days.
This corresponds to 3,0 mg flubendazole/kg bw/day (for a standard food consumption of 0.025 kg/day in a 0,5 kg pheasant).

Pre-dilution to incorporate in the feed in the proportion not less than 5 kg/tonne (i.e. 0.5% m/m).
To ensure the administration of the correct dose, body weight should be determined as accurately as possible. If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly in order to avoid under- or overdosing.

11. Advice on correct administration

Mix well with the feed to ensure a homogeneous distribution.

12. Withdrawal period(s)

Meat and offal:
Pigs: 3 days
Chickens: 5 days
Turkeys, geese, pheasants and partridges: 7 days
Chicken eggs: 0 days

Not for use in other poultry laying eggs for human consumption.

13. Special storage precautions

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

14. Special warning(s)

Special warnings for each target species:
Strategies that should be avoided because they might lead to an increased risk of development of resistance to anthelmintic drugs include:
- Too frequent and repeated use of anthelmintics from the same class over an extended period of time

- Underdosing

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.
Selection of resistant genes leading to the development of resistance can ultimately result in ineffective anthelmintic therapy.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Contact with this product may cause skin sensitisation and/or skin and eye irritation. People with known hypersensitivity (allergy) to flubendazole should avoid contact with the veterinary medicinal product.
When handling or mixing, care should be taken to avoid direct contact with the skin and eyes and inhalation of any dust. Protective clothing, including overalls, impervious gloves, safety glasses and a face-mask should be worn. It is recommended to use 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.
Do not smoke, eat or drink while handling the product.
Wash your hands after using the product or handling the medicated feed.
If symptoms appear after exposure, such as a skin rash, consult a physician and take the package leaflet or label with you. Inflammation of the face, lips and eyes or respiratory distress are more serious signs that require urgent medical attention.

Pregnancy and lactation
The safety of the veterinary medicinal product has not been established during pregnancy, lactation and lay.
Use according to the benefit/risk assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes):
Overdose of ten times therapeutic dose is unlikely to cause adverse reaction. At higher doses, gastrointestinal disorders may occur, which disappear as soon as treatment is interrupted.

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

15. Special precautions for the disposal of unused product or waste materials, if any

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

16. Date on which the label was last approved

28 November 2020

17. Other information

Bags of 25 kg

Drug premixes for animal feed.

18. 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.
Administration by a veterinary surgeon or under their supervision.

Consideration should be given to official guidance on the incorporation of medicated premixes in final feeds.

19. The words “Keep out of the sight and reach of children”

Keep out of the sight and reach of children.

20. Expiry date

EXP {month/year}

Shelf life after opening the immediate packaging: use immediately
Shelf life after incorporation into meal or pelleted feed: 3 months

21. Marketing authorisation number(s)

Vm 43877/4013

22. Manufacturer’s batch number

Batch:

Approved 23 December 2020