

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

**BAG**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

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

**2. COMPOSITION**

Each gram contains:

**Active substance:**  
Flubendazole 50 mg

Premix for medicated feeding stuff.

**3. PACKAGE SIZE**

25 kg

**4. TARGET SPECIES**

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

**5. INDICATIONS FOR USE**

**Indications for use**

Pig: treatment of pig helminthiasis caused by:

*Ascaris suum*  
*Hyostrongylus rubidus*  
*Oesophagostomum dentatum*  
*Trichuris suis*  
*Strongyloides ransomi*  
*Metastrongylus apri*

Chickens, turkeys, geese, partridges, pheasants: 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 veterinary medicinal product is used.

The product is registered for the treatment of adult stages of the helminth species, and, in case of *Ascaridia galli*, all intestinal larval stages (L2, L3 and L4) and adult stages.

## 6. CONTRAINDICATIONS

### Contraindications

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

## 7. SPECIAL WARNINGS

### Special warnings

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each herd/flock.

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.

For an effective control of roundworms in poultry, additional measures regarding disinfection, management and biosecurity are necessary, as advised by the prescribing veterinarian.

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Contact with this veterinary medicinal 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 halfmask 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 veterinary medicinal product. Wash your hands after using the veterinary medicinal 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:

Overdose of ten times therapeutic dose is unlikely to cause an adverse reaction. At higher doses, gastrointestinal disorders may occur, which disappear as soon as treatment is interrupted.

#### 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**

Reporting adverse events is important. It allows continuous safety monitoring of a 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 using the contact details on this label, or via **your national reporting system** {national system details}.

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

### **Dosage for each species, routes 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 a correct dosage, 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.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of flubendazole may need to be adjusted accordingly.

## 10. ADVICE ON CORRECT ADMINISTRATION

### Advice on correct administration

Mix well with the feed to ensure a homogeneous distribution.

## **11. WITHDRAWAL PERIODS**

### **Withdrawal periods**

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 birds producing or intended to produce eggs for human consumption.

## **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.

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.

## **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 national collection systems applicable to the veterinary medicinal product concerned.

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**

To be supplied only on veterinary prescription. Administration by a veterinary surgeon or under their supervision.

## 15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

### Pack sizes

Bags of 25 kg

Vm 43877/3000

## 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](http://www.gov.uk).

## 17. CONTACT DETAILS

### Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Kernfarm B.V.  
De Corridor 14D  
3621 ZB Breukelen  
The Netherlands  
For UK(NI): [+44 7543 556682](tel:+447543556682)

Manufacturer responsible for batch release:

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

## 18. OTHER INFORMATION

### Other information

Drug premixes for animal feed.

## 19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

**20. EXPIRY DATE**

Exp {mm/yyyy}

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

**21. BATCH NUMBER**

Lot {number}

*Gavin Hall*  
Approved: 06 July 2024