SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Flubendazole 50 mg
For the full list of excipients, see section 6.1

Excipients:

Qualitative composition of excipients and other constituents
Calcium carbonate
Soya-bean oil, refined
Silica, Hydrophobic colloidal

White to off-white granulated powder.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

Pigs: 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.

3.3 Contraindications

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

3.4 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 veterinary medicinal 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.

3.5 Special precautions for use

Special precautions for safe use in 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 the 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 veterinary medicinal product.
Wash your hands after using the veterinary medicinal product or handling the medicated feed.
In case of skin and/or eye contact, immediately rinse with plenty of water.
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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None described.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

This veterinary medicinal product is intended to be used for the preparation of medicated feed.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

ATCvet code: QP52AC12.

4.2 Pharmacodynamics

Flubendazole is a synthetic anthelmintic belonging to the benzimidazole carbamates which acts by inhibiting the microtubular assembly in absorptive cells of nematodes.
Flubendazole acts by binding to tubulin, the dimeric subunit protein of the microtubules. It inhibits microtubular assembly in absorptive cells: i.e. of intestinal cells of nematodes. This is shown by disappearance of cytoplasmic microtubules, accumulation of secretory granules in the cytoplasm due to a block in their transport, leading to an impaired coating of the cellular membrane and a decreased digestion and absorption of nutrients. Irreversible lytic degeneration of the cell, due to the accumulation of secretory substances (hydrolytic and proteolytic enzymes), results in the death of the parasite. These changes are relatively fast and are primarily seen in those organelles directly involved in the secretory and absorptive functions of the cells. In contrast the changes are not seen in host cells.

4.3 Pharmacokinetics

When administered orally, flubendazole is practically not absorbed in the gastrointestinal tract (95% of the dose is detected in the intestines 2 hours after administration) and is excreted mainly in the faeces in unaltered form. The absorbed fraction is rapidly metabolised. The elimination half-life of the unaltered veterinary medicinal product is 6 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after incorporation into meal or pelleted feed: 3 months.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Multi-layer paper bag with inner bag of low-density polyethylene.
Format:
Bag of 25 kg

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Kernfarm B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 43877/3000

8. DATE OF FIRST AUTHORISATION

23 January 2020

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall

Approved: 06 July 2024