SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenvet 5 % w/w Premix for Medicated Feeding Stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance:
Flubendazole 50 mg

Excipient:
Titanium dioxide 20 mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff
White to slightly yellow powder.

4. CLINICAL PARTICULARS

4.1 Target species

Pheasant, partridge, chicken, goose, and turkey.

4.2 Indications for use, specifying the target species

Flubendazole is a broad spectrum anthelmintic, effective against mature and immature stages and eggs of the following nematodes of chickens, turkeys, geese, partridges and pheasants:

In the gastrointestinal tract:	*Ascaridia galli, Heterakis gallinarum, Capillaria* spp*., Amidostomum anseris* and *Trichostrongylus tenuis.*
In the respiratory tract:	*Syngamus trachea*

4.3 Contraindications

None known

4.4 Special warnings for target species

None.

4.5 Special precautions for use

None.

i. Special precautions for use in animals

None.

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

Accidental ingestion by humans should be avoided. May cause sensitisation by skin contact. May cause skin and eye irritation. Avoid direct skin contact. Wear overalls, safety glasses and impervious gloves when mixing and handling the product. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water. If the operations involve potential exposure to dust, wear either a disposable filter and half-mask respirator conforming to European Standard EN149, or a non-disposable respirator to European Standard EN140 fitted with a filter to EN143.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration only.

For incorporation into dry feed at a registered mill.
A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products, must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

Pheasants and partridges:
1.2 kg of the product is incorporated into 1 tonne of feeding stuff to provide 60g flubendazole per tonne of feed. Treat for 7 consecutive days.

Chickens and geese:
600 g of the product is incorporated into 1 tonne of feeding stuff to provide 30g flubendazole per tonne of feed. Treat for 7 consecutive days.
Turkeys:
400 g of the product is incorporated into 1 tonne of feeding stuff to provide 20g flubendazole per tonne of feed. Treat for 7 consecutive days.

On infected premises treatment at 3 weekly intervals may be necessary to control worm infestation.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Flubendazole is an analog of mebendazole for which the side effects of overdose include transient gastrointestinal abnormalities.

4.11 Withdrawal period(s)

Birds must not be slaughtered for human consumption during treatment.
Chickens, turkeys, geese, partridges and pheasants: Meat: 7 days
Chickens eggs: zero days

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anthelmintic

ATCvet code: QP52AC12.

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.

5.2 Pharmacokinetic particulars

Flubendazole is very poorly soluble in aqueous systems, such as the gastrointestinal tract, which results in a low dissolution rate and a very low absorption. This is reflected by the high faecal excretion of unchanged parent drug. The very small fraction absorbed is extensively metabolised by first pass metabolism in the liver, involving carbamate hydrolysis and ketone reduction. The biotransformation products are conjugated to glucuronides or sulphate conjugates and excreted in the bile and the urine.

The excretion in urine is relatively low and consists almost exclusively of metabolites with only small amounts of unchanged compound. In pigs, highest tissue levels are measured in liver and kidneys. The half life of flubendazole in tissues is 1 - 2 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium dioxide (E171)
Lactose monohydrate
Sodium lauryl sulphate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of product as packaged for sale: 5 years
Shelf life after incorporation into meal or pelleted feed: 8 weeks

6.4 Special precautions for storage

Do not store above 25 °C.
Store in tightly closed original containers.
The product will remain stable in the finished feed for eight weeks.

The product can be incorporated into pelleted feed, preconditioned with steam for up to 5 minutes at a temperature of 77 °C and can withstand pelleting temperatures up to 116 °C. When used as recommended, this product should only be incorporated by approved manufacturers.

6.5 Nature and composition of immediate packaging

2 kg low density polyethylene/polyethylene terephthalate bags.
Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

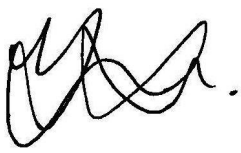
Vm 43877/4010

9. DATE OF FIRST AUTHORISATION

24 January 2017

10. DATE OF REVISION OF THE TEXT

February 2022



Approved: 01 February 2022