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

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Sodium lauryl sulphate

White to slightly yellow powder.

3. CLINICAL INFORMATION

3.1 Target species

Pheasant, partridge, chicken, goose, and turkey.

3.2 Indications for use for each 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*

3.3 Contraindications

None known

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None.

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

Accidental ingestion by humans should be avoided.
This product may cause sensitisation by skin contact and may cause skin and eye irritation. Avoid direct skin contact.
Personal protective equipment consisting of overalls, safety glasses and impervious gloves should be worn when mixing and handling the product.
In case of skin contact, wash the affected area with water. In case of eye contact, rinse thoroughly and immediately with water.
To avoid exposure to dust, personal protective equipment consisting of 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 should be worn when handling the product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pheasant, partridge, chicken, goose, and turkey:

None known.

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

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

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

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

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

Not applicable.

3.12 Withdrawal periods

Meat and offal: 7 days

Eggs: Chickens: zero days
Not authorised for use in pheasants, partridges, geese and turkeys producing eggs for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 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

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

The veterinary medicinal 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 veterinary medicinal product should only be incorporated by approved manufacturers.

5.4 Nature and composition of immediate packaging

25kg and 12kg Multilayered bag – LDPE/Aluminum/kraft paper

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 52127/5108 (GB)
Vm 52127/3043 (NI)

8. DATE OF FIRST AUTHORISATION

17 September 2000

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

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 08 August 2025