1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenol 50 mg/g Premix for Medicated Feeding Stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
Flubendazole 50 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium Lauryl Sulphate
Lactose Monohydrate

White powder.

3. CLINICAL INFORMATION

3.1 Target species

Pigs and poultry.

3.2 Indications for use for each target species

Flubendazole is a broad spectrum anthelmintic, effective against mature and immature stages of the following nematodes of the gastro-intestinal and respiratory tract:

In pigs: *Ascaris suum,* (large roundworm) including migrating larvae, *Hyostrongylus rubidus,* (red stomach worm), *Oesophagostomum dentatum* (nodular worm). *Trichuris suis* (whipworm), *Strongyloides ransomi* (adult) and *Metastrongylus apri* (lungworm).

In poultry: *Syngamus trachea* (gapeworm), *Ascaridia galli* (large roundworm), *Heterakis gallinarum* (caecal worm), *Capillaria Gallinarum* (hair worm), *Amidostomum anseris* (gizzard worm), *Trichostrongylus tenuis.*

Flubendazole is ovicidal.

3.3 Contraindications

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

3.4 Special warnings

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- 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 tests strongly suggest resistance

to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None known.

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

Accidental ingestion by humans should be avoided. Avoid direct skin contact. Personal protective equipment consisting of overalls, safety glasses and impervious gloves should be worn when mixing and handling the veterinary medicinal product. Wash affected parts if skin contact occurs. If accidental eye contact occurs, immediately rinse thoroughly with water. If the operation involves potential exposure to duct, either a half mask respirator (European Standard EN 149) with disposable filter, or a non-disposable respirator (European Standard EN 140) fitted with a filter (EN 143) should be worn.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

3.6 Adverse events

Pigs and Poultry:
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 label for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Pigs:
Group treatment:
Incorporation: add 600g of the veterinary medicinal product to at least 5 kg of one of the feed ingredients and mix well. Thoroughly mix this premix with the remaining ingredients making in all one tonne of medicated feed, which can then be fed as mash or pellets. This gives 30 mg flubendazole per kg of finished feed.

Dosage:

a) Breeding stock - feed for 10 consecutive days to control all worm species above.
b) Weaners and fattening pigs - feed for 5 consecutive days. In the event of a heavy *Trichuris* infestation, feed for 10 consecutive days.

Treatment frequency: Twice a year unless recommended otherwise by a veterinary surgeon. Pigs brought onto the premises should be treated on arrival and before mixing with other animals.

Treatment of clinical worm infestations:
Treat relevant infestations at the following intervals:
Lungworm (*Metastrongylus apri)* - every 3-4 weeks
Nodular worm (*Oesophagostomum dentatum)* - every 2 months
Large roundworm (*Ascaris suum)* - every 2 months
Red stomach worm (*Hyostrongylus rubidus)* - every month
Whipworm *(Trichuris suis)* - every 6 weeks

Poultry:
The veterinary medicinal product should be thoroughly mixed into the feed in order to obtain a homogeneous mixture.

Chickens and geese
30 g flubendazole per tonne feed (30ppm) during 7 consecutive days. 600 g of the veterinary medicinal product is incorporated into 1 tonne of feeding stuff to provide 30 g flubendazole per tonne of feed.

Pheasants & partridges
60 g flubendazole per tonne feed (60ppm) during 7 consecutive days.
1.2 kg of the veterinary medicinal product is incorporated into 1 tonne of feeding stuff to provide 60 g flubendazole per tonne of feed.

Turkeys
20 g flubendazole per tonne feed (20ppm) during 7 consecutive days.
400 g of the veterinary medicinal product is incorporated into 1 tonne of feeding stuff to provide 20 g flubendazole per tonne of feed.
On infected premises treatment at 3 weekly intervals may be necessary to control worm infestation.
Regular faecal examination is advocated to know which worms are present on the farm so that specific measures may be taken to prevent re-infection.

The veterinary medicinal product can be incorporated into pelleted feed, preconditioned with steam 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 authorised manufacturers.

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

Flubendazole has a low acute oral toxicity and is well tolerated in the target species. In situations where accidental overdose is suspected of having occurred, there is no antidote and treatment should be symptomatic.

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

Pigs & poultry:
Meat and offal: 7 days.
Eggs: Zero days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AC12

4.2 Pharmacodynamics

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 or the tegumental cells of cestodes. 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 a 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 to 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: 2 months.

5.3 Special precautions for storage

Store in tightly closed original containers.
Do not store above 25°C.

5.4 Nature and composition of immediate packaging

Container: Multi-layered paper bag with internal low-density polyethylene (LDPE) layer or a laminated polyethylene (PE)/polyethylene-terephalate (PET) bag.
Container size: 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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/006/001

8. DATE OF FIRST AUTHORISATION

25/05/2012

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

05/12/2024

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).