Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenol 5 % w/w Premix for Medicated Feeding Stuff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance		
Flubendazole	50	mg
Excipients		
Titanium dioxide (E171)	20	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff.
White powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Pig and Poultry.

4.2 Indications for use, specifying the 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, Ascaridia galli, Heterakis gallinarum, Capillaria gallinarum, Amidostomum anseris, Trichostrongylus tenuis.*

Flubendazole is ovicidal.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

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. 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 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Pigs:

Group treatment:

I Incorporation: add 600g of Flubenol 5% to at least 5kg 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.

II 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.

III 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.

IV 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:

Flubenol 5% 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 Flubenol 5% 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 Flubenol 5% 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 Flubenol 5% 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 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 product should only be incorporated by authorised manufacturers.

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

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.

4.11 Withdrawal period(s)

Pigs and poultry must not be slaughtered for human consumption during treatment. Pigs & poultry may be slaughtered for human consumption only after 7 days from the last treatment. There is no withholding period required for eggs (that is, zero days).

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, flubendazole. ATCvet code: QP52AC12

5.1 Pharmacodynamic properties

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.

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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Lauryl Sulphate
Titanium Dioxide (E171) Lactose Monohydrate

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years
Shelf-life after incorporation into meal: 2 months

6.4 Special precautions for storage

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

6.5 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.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 29th September 2009

10 DATE OF REVISION OF THE TEXT

June 2018