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 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

Pigs

4.2 Indications for use, specifying the target species

Flubendazole is a broad spectrum anthelmintic for oral administration, active against mature and immature stages of the following nematodes of the gastro-intestinal tract of the pig:
Ascaris suum (large roundworm)
Hyostrongylus rubidus (red stomach worm)
Oesophagostomum dentatum (nodular worm)
Trichuris suis (whip worm)
Strongyloides ransomi (threadworm) (adult).
Metastrongylus apri (lungworm).

Flubendazole is ovicidal.

4.3 Contra-indications

Not applicable.

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.

Dosage
The standard recommended total dosage is 5 mg flubendazole per kg bodyweight. The amount of product to be incorporated should be calculated according to the average bodyweight of the pigs to be treated.

Incorporation and dosing instructions
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 over-dosing.
As a guide, the following incorporation rates are suggested:

Standard dosing regime

Incorporation:
Add 600 g of Flubenol 5 %w/w Premix 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.

Breeding stock should be treated for 10 consecutive days. Weaners and fattening pigs –should be treated for 5 consecutive days, or the event of a heavy *Trichuris* infestation, for 10 consecutive days.

Variable dosing regime

To facilitate feeding for different lengths of time to suit the intervals between feed deliveries, the standard dosage can be divided and administered over differing periods of time, as shown below.

Incorporation:
Add the required amount of Flubenol 5% Premix to at least 5kg of one of the feed ingredients. 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.

a) Breeding stock

Amount of Flubenol 5 % w/w to add to each 5 kg premix for making up each tonne of final feed	Flubendazole inclusion rate in final feed (mg/kg)	Duration of treatment (days)	Total dose of flubendazole (mg/kg bodyweight)	Uses
400 g	20	14	5	*Ascaris suum, Oesophagostomum dentatum* and *Hyostrongylus rubidus*
300 g	15	21	5	
200 g	10	28	5	

b) Weaners and fattening pigs

Amount of Flubenol 5 % w/w to add to each 5 kg premix for making up each tonne of final feed	Flubendazole inclusion rate in final feed (mg/kg)	Duration of treatment (days)	Total dose of flubendazole (mg/kg bodyweight)	Uses
200 g	10	14	5	*Ascaris suum, Oesophagostomum dentatum* and *Hyostrongylus rubidus*
150 g	7.5	21	5	

In the event of a heavy *Trichuris* infestation, use 600 g/tonne (30 mg/kg final feed) for 10 days.

Treatment frequency:
Pigs should be treated 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	every 3 - 4 weeks
Nodular worm	every 2 months
Large round worm	every 2 months
Red stomach worm	every month
Whipworm	every 6 weeks

Consult a veterinary surgeon for initial identification of problem species.

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)

Animals must not be slaughtered for human consumption during treatment.
Pigs may be slaughtered for human consumption only after 7 days from the last treatment.

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

Container: Multilayered bag – LDPE/Aluminum/kraft paper
Container size: 25 kg.

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

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

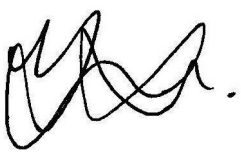
Vm 00879/4179

9. DATE OF FIRST AUTHORISATION

17 September 1985

10. DATE OF REVISION OF THE TEXT

September 2022



Approved: 01 September 2022