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

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

Pigs

3.2 Indications for use for each 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.

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. 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 veterinary medicinal 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:
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.

Dosage
The standard recommended total dosage is 5 mg flubendazole per kg bodyweight. The amount of the veterinary medicinal 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 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.

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 the veterinary medicinal product 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 the veterinary medicinal product 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 the veterinary medicinal	Flubendazole inclusion rate	Duration of	Total dose of	Uses

product to add to each 5 kg premix for making up each tonne of final feed	in final feed (mg/kg)	treatment (days)	flubendazole (mg/kg bodyweight)	
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.

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.

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

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

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 Europe Ltd

7. MARKETING AUTHORISATION NUMBER

Vm 00879/4179

8. DATE OF FIRST AUTHORISATION

17 September 1985

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

January 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: 26 March 2025