SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flubenol 5 % w/w Oral Powder for Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	mg/g
Active ingredient/s:	
Flubendazole	50
Excipient/s:	
Titanium dioxide (E171)	20

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder
White powder

4. CLINICAL PARTICULARS

4.1 Target species

Pigs

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 tract:
Ascaris suum, (large roundworm) including migrating larvae, *Hyostrongylus rubidus*, (red stomach worm), *Oesophagostomum dentatum* (nodular worm), *Trichuris suis* (whipworm) and *Strongyloides ransomi* (threadworm) (adult).
Flubendazole is ovicidal.

4.3 Contraindications

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

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, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

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 test(s) 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

i. Special precautions for use in animals

Not applicable.

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. 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 dust, wear either a disposable filter on a half mask respirator, conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 fitted with a filter to EN 143.

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

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
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 overdosing.

Individual treatment (single administration):

i. Dosage:

Add 1 g of the veterinary medicinal product for each 10 kg bodyweight onto the finished feed, as a single animal dose. (This is equivalent to 5 mg of flubendazole per one kg bodyweight). One 13 g measuring spoon treats one 130 kg sow.

ii. 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. 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.

iii. Treatment of clinical worm infestations:

Treat relevant infestations at the following intervals:

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.

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 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

Pharmacotherapeutic group: Benzimidazoles and related substances; Flubendazole.

ATCvet code: QP52AC12

Flubendazole is a synthetic anthelmintic belonging to the benzimidazole carbamates.

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 laurilsulfate
Titanium dioxide
Lactose monohydrate

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.
Prepare immediately before use; discard any unused feed at the end of the day.

6.4 Special precautions for storage

Keep the container tightly closed.
Do not store above 25 °C.

6.5 Nature and composition of immediate packaging

Container:	White opaque polypropylene tub containing 600 g Flubenol 5 % as a white powder.
Closure:	White opaque low-density polyethylene cap (snap-on) for the tub.

Dosing device: 20 ml measuring spoon (equivalent to 13 g Flubenol)
Container size: 600 g

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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 00879/4183

9. DATE OF FIRST AUTHORISATION

17 September 2000

10. DATE OF REVISION OF THE TEXT

October 2020

Approved: 01 October 2020