SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fluboral 200 mg/ml, suspension for use in drinking water for pigs and chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Flubendazole 200.0 mg

Excipients:
Methyl parahydroxybenzoate (E218) 2.7 mg
Propyl parahydroxybenzoate 0.75 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for use in drinking water
White to off-white suspension

4. CLINICAL PARTICULARS

4.1 Target species

Pigs and chickens.

4.2 Indications for use, specifying the target species

Chickens:
Treatment of helminthiasis caused by:
- *Ascaridia galli* (adult stages)
- *Heterakis gallinarum* (adult stages)
- *Capillaria* spp. (adult stages)

Pigs:
Treatment of helminthiasis caused by *Ascaris suum* (adult and L4 intestinal stages).

4.3 Contraindications

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

4.4 Special warnings for each target species

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each herd/flock.

The use of this product should take into account local information about susceptibility of the target parasites, where available.

It is recommended to further investigate cases of suspected resistance, using an appropriate diagnostic method (e.g. Faecal Egg Count Reduction Test (FECRT)). 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.
Optimal results can only be achieved if strict rules of hygiene are applied.

Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

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

The veterinary medicinal product can cause skin and eye irritation, and hypersensitivity reactions.
Direct contact with the product should be avoided. People with known hypersensitivity to flubendazole should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
Wash hands after use.
In the event of eye contact, rinse thoroughly with water and if conjunctival redness persists, seek medical advice.

iii) Other precautions

Due to concerns for the environment when the product is used in free range poultry or pigs, animals must be kept indoors during the treatment period and for 1 day after last treatment.

4.6 Adverse reactions (frequency and seriousness)

Chickens:

Undetermined frequency (cannot be estimated from the available data):	Development disorders of the feathers

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 its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rabbits and rats have not produced any evidence of embryotoxicity, teratogenicity at therapeutic doses. High dosages gave equivocal results. In laboratory studies in rats, there were no effects on pups during lactation.
The safety of the veterinary medicinal product has been established during pregnancy, lactation and lay.

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

Laying birds:
Can be used during lay.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amount(s) to be administered and administration route

In drinking water use.

Dosage:

Chickens:
1.43 mg flubendazole (= 0.00715 ml product or 0.00775 g product) per kg body weight daily for 7 consecutive days, administered orally in drinking water, i.e. 1 ml of the product per 140 kg body weight daily for 7 days.

Pigs:
a. Treatment of adult stages and L4 intestinal stages of *Ascaris suum*
1 mg flubendazole (= 0.005 ml product or 0.00542 g product) per kg body weight daily for 5 consecutive days, administered orally in drinking water, i.e. 1 ml of the product per 200 kg body weight daily for 5 days.

b. Treatment of adult stages of *Ascaris suum*
2.5 mg flubendazole (= 0.0125 ml product or 0.0136 g product) per kg body weight daily for 2 consecutive days, administered orally in drinking water, i.e. 2.5 ml of the product per 200 kg body weight daily for 2 days.

Based on the recommended dose and the number and weight of animals to be treated, the required daily volume of veterinary medicinal product should be calculated according to the following formula:

ml of veterinary medicinal product required per day	Dose (mg/kg BW)	Total BW (kg) of animals to be treated
	200 mg/ml (concentration of the veterinary medicinal product)	

In case a weighing scale is used:
g of product required per day = ml of product required per day x 1.084

Method of administration:

Prior to and after the period of treatment make sure the water distribution system is cleaned.
Each day a fresh suspension should be prepared.
The container should be shaken for 30 seconds before use.

1. Tanks:
Add water to the daily required amount of product until the volume equals the quantity of water usually consumed by the animals in approximately 4 hours.

2. Dosing pumps:
Prepare a stock suspension according to the flow rate of the pump. For example: at a 1% flow rate add water to the daily required amount of product until the volume equals 1% of the quantity of water usually consumed by the animals in approximately 4 hours. The maximal concentration of the product in the drinking water should be 150 ml/L.

Stir with a manual mixer (whisk) for about 5 seconds to obtain a white milky homogenous mixture.

In order to ensure administration of the correct dose, a substantial water flow must be present in the drinking water system:
-administer the product when the water consumption of the animals is highest
-if needed withhold drinking water for 2 hours before treatment to stimulate water intake

Make sure the medicated water is fully consumed to avoid underdosing. The exact time period over which the product is administered each day is not critical but all animals should have sufficient time to drink.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

Accuracy of the dosing device should be thoroughly checked. The use of suitably calibrated measuring equipment is recommended.

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

In chickens, no undesirable effects have been observed after administration of up to 4 times the recommended dose for 14 days. Even at doses 4 times the recommended dose, egg quality is not altered. Only a reduction in egg weight and a slight decrease in egg production can be observed with doses of twice the recommended dose and over. Egg weight returns to normal when treatment is discontinued.
In pigs, no undesirable effects have been observed at five times the highest dose administered for three times the intended duration (12.5 mg/kg administered for 6 consecutive days).
In the event of a massive overdose, mild transient diarrhoea can occur by the 2nd day of treatment, possibly lasting for 7 to 12 days without affecting the behaviour or performance of the animals.

4.11 Withdrawal period(s)

Pigs:
Meat and offal: 1mg/kg for 5 days: 4 days
2.5 mg/kg for 2 days: 5 days
Chickens:
Meat and offal: 2 days
Eggs: zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Benzimidazoles and related substances

ATC Vet Code: QP52AC12

5.1 Pharmacodynamic properties

Flubendazole is a benzimidazole anthelmintic. It acts by binding to tubulin of the parasite, the dimeric subunit protein of the microtubules. It inhibits micro tubular assembly in absorptive cells: i.e. in 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 cells of the host.
Another tubulin-related effect is the strong inhibition of egg hatch by inhibition of microtubule-dependent processes in the developing worm egg (cell division).

5.2 Pharmacokinetic particulars

Flubendazole is poorly soluble in aqueous systems, such as the gastrointestinal tract, which results in a low dissolution rate and a low absorption. This is reflected by the high faecal excretion of unchanged parent drug. The 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 with the bile and the urine.
The excretion with urine is relatively low and consists almost exclusively of metabolites with only small amounts of unchanged compound.
In pigs and chicken, the half-life of flubendazole and its metabolites in plasma is 12 hours to 2 days.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate
Propylene glycol
Poloxamer 407
Sodium chloride
Simethicone (as an emulsion)
Purified water

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 6 months
Shelf life after dilution according to directions: 24 hours

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Semi-transparent high density polyethylene bottle of 250 ml closed with white high density polyethylene screw-cap containing low density polyethylene sealing element.
Semi-transparent high density polyethylene bottle of 1 litre closed with white high density polyethylene screw-cap containing low density polyethylene sealing element.
Semi-transparent high density polyethylene canister of 3 litre closed with white polypropylene screw-cap containing low density polyethylene sealing element.

Not all pack sizes may be marketed.

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

DANGEROUS to aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 10434/5005

9. DATE OF FIRST AUTHORISATION

19 April 2023

10. DATE OF REVISION OF THE TEXT

April 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

POM-V

Approved 19 April 2023