## 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:**

| **Qualitative composition of excipients and other constituents** | **Quantitative composition if that information is essential for proper administration of the veterinary medicinal product** |
|---|---|
| Methyl parahydroxybenzoate (E218) | 2.7 mg |
| Propyl parahydroxybenzoate | 0.75 mg |
| Propylene glycol | |
| Poloxamer 407 | |
| Sodium chloride | |
| Simethicone (as an emulsion) | |
| Purified water | |

White to off-white suspension

## 3. CLINICAL INFORMATION

### 3.1 Target species

Pigs and chickens.

### 3.2 Indications for use for each 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)

### 3.3 Contraindications

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

### 3.4 Special warnings

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.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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.

Special precautions for the protection of the environment:
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.

### 3.6 Adverse events

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.

### 3.7 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.

### 3.8 Interaction with other medicinal products and other forms of interaction

None known.

### 3.9 Administration routes and dosage

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:

$$\text{ml of veterinary medicinal product required per day} = \frac{\text{Dose (mg/kg BW)} \times \text{Total BW (kg) of animals to be treated}}{\text{200 mg/ml (concentration of the veterinary medicinal product)}}$$

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.

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

### 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

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

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QP52AC12

### 4.2 Pharmacodynamics

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).

### 4.3 Pharmacokinetics

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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

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

### 5.2 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

### 5.3 Special precautions for storage

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

### 5.4 Nature and composition of immediate packaging

Semi-transparent HDPE bottle of 250 ml closed with white HDPE screw-cap containing LDPE sealing element.
Semi-transparent HDPE bottle of 1 litre closed with white HDPE screw-cap containing LDPE sealing element or not.
Semi-transparent HDPE canister of 3 litre closed with white PP screw-cap containing LDPE sealing element or with white HDPE screw cap..

Not all pack sizes may be marketed.

### 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 or household waste.
The veterinary medicinal product should not enter water courses as flubendazole may be dangerous for fish and other aquatic organisms.
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

Dechra Regulatory B.V.

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA22622/036/001

## 8. DATE OF FIRST AUTHORISATION

05/05/2023

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

16/10/2026

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription
Detailed information on this veterinary medicinal product is available in the Union Product Database.