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Flimabend 100mg Suspension for Pigs & Chickens

Species:	Chickens, Pigs
Therapeutic indication:	Pharmaceuticals: Antimicrobials: Oral preparations: Others
Active ingredient:	Flubendazole
Product:	Flimabend 100mg Suspension for Pigs & Chickens
Product index:	Flimabend 100mg Suspension for Pigs & Chickens
Pig - meat:	See Notes
Poultry - meat:	Meat & Offal: 2 days
Poultry - eggs:	Zero days
Withdrawal notes:	Pigs: dose 1 mg/kg body weight for 5 days: 3 days/dose 2.5 mg/kg body weight for 2 days: 4 days

Presentation

Suspension for use in drinking water. White to brownish white suspension. Each gram contains 100mg flubendazole, and 2mg Methyl parahydroxybenzoate [E218], 5mg Sodium benzoate [E211] and 0.1mg Disodium edetate as excipients.

Uses

Chickens [layer hens, chickens for reproduction, pullets, broilers]

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

Pigs [piglets, pigs for fattening, pregnant sows]

- Treatment of helminthiasis caused by *Ascaris suum* (adult and intestinal larval stages) in piglets, fattening pigs and pregnant sows.

Dosage and administration

Hens/Chickens:

1.43 mg flubendazole (= 14.3 mg product) per kg body weight daily via oral administration during 7 days i.e. 1 g of the product per 70 kg body weight daily for 7 days.

Pigs:

a) Treatment of helminthiasis caused by *Ascaris suum* (adult stages and intestinal larval stages) in piglets, pigs for fattening and pregnant sows.

1 mg flubendazole (= 10 mg product) per kg body weight daily via oral administration during 5 days, i.e. 1 g of the product per 100 kg body weight daily for 5 days.

b) Treatment of helminthiasis caused by *Ascaris suum* (adult stages) in piglets and pigs for fattening.

2.5 mg flubendazole (= 25 mg product) per kg body weight daily via oral administration during 2 days, i.e. 2.5 g of the product per 100 kg body weight daily for 2 days.

Pigs should be grouped according to their bodyweight and dosed accordingly, in order to prevent under or overdosing.

Calculate the dosage accurately with the following formula:

$$\frac{\text{...mg [product]} \quad \times \text{Average bw (kg) of the treated animals}}{\text{per kg bw/day} \quad \text{average quantity of drinking water (litre/animal) consumed in } 4 \text{ h}} = \frac{\text{... mg [product]}}{\text{per litre drinking water}}$$

This will result in a concentration of flubendazole between 20 and 200 mg per litre.

Method of administration:

Administration in drinking water

1] The required quantity of the product is in function of the estimated body weight of the total group animals (see table below for guidance).

Hens/Chickens, 7 days treatment:

Total weight of chickens	Amount of medication to be used [g/day]	Total amount of medication used [g/7 days]
1400kg	20g	7 x 20g
7000kg	100g	7 x 100g
35000kg	500g	7 x 500g

Pigs, 5 days of treatment:

Total weight of pigs	Amount of medication to be used [g/day]	Total amount of medication used [g/5 days]
2000kg	20g	5 x 20g
10000kg	100g	5 x 100g
50000kg	500g	5 x 500g

Pigs, 2 days of treatment:

Total weight of pigs	Amount of medication to be used [g/day]	Total amount of medication used [g/2 days]
2000kg	50g	2 x 50g
4000kg	100g	2 x 100g
40000kg	1000g	2 x 1000g

2) Each day a predilution is prepared containing the daily required dose of the product admixed in 10 to 100 times its weight in water depending on the distribution system. For example: for 500 g of the product, add 5 litres to 50 litres of water.

3) Squeeze the sachet gently before use and then empty the contents into the predilution recipient.

4) If less than entire sachet is required, the required dose should be measured by suitably calibrated weighing equipment.

5) Stir the predilution vigorously with a manual mixer (whisk) for 2 minutes to obtain a white milky homogenous mixture.

6) This predilution must be distributed via the general water supply system:

Tanks: add the predilution to the quantity of water usually consumed by the animals over a period of up to 4 hours.

Dosing pumps: adjust the flow rate of the pump to distribute the predilution over a period of up to 4 hours.

In order to ensure administration of the correct dose, a substantial water flow must be present in the drinking water system. Administration of the product over a period of up to 4 hours on each treatment day, at times when water consumption is likely to be highest prevents precipitation of flubendazole in the water delivery system and allows washing out of the drinking water system within a 24 hour period after the period of drug administration is finished.

7) Prior to and after the period of treatment make sure the water distribution system is cleaned.

8) Make sure that all animals in the group receive enough drinking water with the product. Withhold drinking water for 2 hours before treatment to stimulate thirst.

9) The corresponding dose must always be distributed when the water consumption of the animals is highest.

Use during pregnancy and lactation

The safety of the product has been demonstrated in laying hens. The product can be administered to these animals.

Laboratory studies in rabbits and rats have not produced any evidence of embryotoxicity, teratogenicity at therapeutic doses. High dosages gave equivocal results. The safety of the product has not been demonstrated in pregnant sows. In laboratory studies in rats, there were no effects on pups during lactation. The safety of the product has not been assessed in pregnant and lactating sows. The use of the product during pregnancy and lactation should be subject to risk/benefit ration assessment by the responsible veterinarian.

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

Contra-indications, warnings, etc

In chickens, optimal results can only be achieved if strict rules of hygiene are respected in the maintenance of the cages.

In both 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.

Special precautions for use in animals

Development disorders of the feathers cannot be fully excluded after the administration of flubendazole.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Direct contact with product should be avoided. Wear protective gloves while using the product. Wash hands after use.

People with known hypersensitivity to flubendazole should avoid contact with the veterinary medicinal product. In the event of eye contact, rinse thoroughly with water. In case of appearance and persistence of conjunctival redness, seek medical advice and show the package leaflet to the physician.

Overdose

Flubendazole has a low acute oral toxicity.

In hens, no undesirable effects have been observed after administration of up to 15 mg/kg b.w./day flubendazole.

In porcine, no adverse effects have been observed after administration of up to 50 mg/kg b.w./day flubendazole.

In situation when accidental overdose is suspected of having occurred, there is no antidote and treatment should be symptomatic.

Interactions

None known. In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Environmental Safety

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

Withdrawal Periods

Meat & Offal:

Chicken - 2 days

Pigs -

Dose 1 mg/kg body weight for 5 days: 3 days

Dose 2.5 mg/kg body weight for 2 days: 4 days

Eggs: zero days

Pharmaceutical precautions

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

Legal category

Legal category: POM-VPS

Packaging quantities

Cardboard box containing 2 sachets (sachet PE/PET/aluminium/PET) of 20g powder suspension for use in drinking water.

Cardboard box containing 25 sachets (sachet PE/PET/aluminium/PET) of 100g powder suspension for use in drinking water.

Tub containing 750g of powder for suspension for use in drinking water.

Marketing Authorisation Holder (if different from distributor)

KRKA, d.d., Novo mesto

Šmarješka cesta 6

8501 Novo mesto

Slovenia

Further information

Anthelmintics. Benzimidazoles and related substances.

ATCvet code: QP52AC12

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 cells, 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).

Flubendazole is poorly soluble in aqueous systems, such as the gastrointestinal tract, which results in a low distribution 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 chickens, the half-life of flubendazole and its metabolites in plasma is 12 hours to 2 days.

Marketing Authorisation Number

Vm 01656/4042

Significant changes

GTIN

GTIN description: Flimabend 100mg Suspension for Pigs and Chickens(25 x 100g)

GTIN: 03838989648886

GTIN description: Flimabend 100mg Suspension for Pigs and Chickens(4 x 750g)

GTIN: 03838989669058
GTIN description: Flimabend 100mg Suspension for Pigs and Chickens[2 x 20g]
GTIN: 3838989724146

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