LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX containing sachets (2 x 20 g, 24 x 20 g, 2 x 50 g, 24 x 50 g, 1 x 100 g, 5 x 100 g, 25 x 100 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLIMABO 100 mg/g suspension for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains 100 mg flubendazole

3. PACKAGE SIZE

2 x 20 g
24 x 20 g
2 x 50 g
24 x 50 g
1 x 100 g
5 x 100 g
25 x 100 g

4. TARGET SPECIES

Pigs (piglets, pigs for fattening, pregnant and lactating sows) and chickens (layer hens, chickens for reproduction pullets, broilers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Pigs (meat and offal):
- dose 1 mg/kg body weight for 5 days: 3 days
- dose 2.5 mg/kg body weight for 2 days: 4 days

Chickens (meat and offal): 2 days
Eggs: zero days.

8. EXPIRY DATE

Exp.

Shelf life after first opening the sachet: Use immediately. Any suspension remaining in the sachet after first opening should be discarded.
Shelf life after dilution according to directions: 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

01656/3063

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABEL for box containing containers (4 x 750 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLIMABO 100 mg/g suspension for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains 100 mg flubendazole

3. PACKAGE SIZE

4 x 750 g

4. TARGET SPECIES

Pigs (piglets, pigs for fattening, pregnant and lactating sows) and chickens (layer hens, chickens for reproduction pullets, broilers).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Pigs (meat and offal):
- dose 1 mg/kg body weight for 5 days: 3 days
- dose 2.5 mg/kg body weight for 2 days: 4 days

Chickens (meat and offal): 2 days
Eggs: zero days.

8. EXPIRY DATE

Exp.
Shelf life after first opening the container: 6 months.
Shelf life after dilution according to directions: 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Name of the marketing authorisation holder:
KRKA, d.d., Novo mesto

14. MARKETING AUTHORISATION NUMBERS

01656/3063

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Label – bag (20 g, 50 g, 100 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLIMABO 100 mg/g suspension for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains 100 mg flubendazole

3. TARGET SPECIES

Pigs (piglets, pigs for fattening, pregnant and lactating sows) and chickens (layer hens, chickens for reproduction, pullets, broilers).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
In drinking water use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Pigs (meat and offal):
- dose 1 mg/kg body weight for 5 days: 3 days
- dose 2.5 mg/kg body weight for 2 days: 4 days

Chickens (meat and offal): 2 days
Eggs: zero days.

6. EXPIRY DATE

Exp.

Shelf life after first opening the sachet: Use immediately. Any suspension remaining in the sachet after first opening should be discarded.
Shelf life after dilution according to directions: 24 hours.

Information about the batch number and date of expiration are shown on the sealed edge of the bag.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Name of the marketing authorisation holder:
KRKA, d.d., Novo mesto

9. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
Label – container (750 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLIMABO 100 mg/g suspension for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Each g contains 100 mg flubendazole

3. TARGET SPECIES

Pigs (piglets, pigs for fattening, pregnant and lactating sows) and chickens (layer hens, chickens for reproduction, pullets, broilers).

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
In drinking water use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Pigs (meat and offal):
- dose 1 mg/kg body weight for 5 days: 3 days
- dose 2.5 mg/kg body weight for 2 days: 4 days

Chickens (meat and offal): 2 days
Eggs: zero days.

6. EXPIRY DATE

Exp.
Shelf life after first opening the container: 6 months.
Shelf life after dilution according to directions: 24 hours.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Name of the marketing authorisation holder:
KRKA, d.d., Novo mesto

9. BATCH NUMBER

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

FLIMABO 100 mg/g suspension for use in drinking water for chickens and pigs

2. Composition

Each g contains 100 mg of flubendazole with 2 mg of methyl parahydroxybenzoate (E218), 5 mg of sodium benzoate (E211) and 0.1 mg of disodium edetate.

White to brownish white suspension.

3. Target species

Pigs (piglets, pigs for fattening, pregnant and lactating sows) and chickens (layer hens, chickens for reproduction, pullets, broilers).

4. Indications for use

In hens/chickens:
Treatment of helminthiasis caused by *Ascaridia galli* (adult stages), *Heterakis gallinarum* (adult stages), *Capillaria* spp. (adult stages).

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

5. Contraindications

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

6. Special warnings

Special warnings:
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 veterinary medicinal 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 to be taken by the person administering the veterinary medicinal product to animals:
Direct contact with veterinary medicinal product should be avoided. Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal 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.

Pregnancy and lactation:
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 product has been demonstrated in pregnant and lactating sows. Can be used in pregnant and lactating sows.

Laying birds:
The safety of the product has been demonstrated in laying hens. Can be used in laying hens.

Interaction with other medicinal products and other forms of interaction:
None known.

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 pigs, no adverse effects have been observed after administration of up to 50 mg/kg b.w./day flubendazole.
In situations where accidental overdose is suspected of having occurred, there is no antidote and treatment should be symptomatic.

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

7. Adverse events

Pigs:
None known.

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. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the the marketing authorisation holder > using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}

8. Dosage for each species, routes and method of administration

Oral use.

Hens/chickens:
1.43 mg flubendazole (= 14.3 mg veterinary medicinal product) per kg body weight daily during 7 days i.e. 1 g of the veterinary medicinal 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):
1 mg flubendazole (= 10 mg veterinary medicinal product) per kg body weight daily during 5 days, i.e. 1 g of the veterinary medicinal product per 100 kg body weight daily for 5 days;

b) Treatment of helminthiasis caused by *Ascaris suum* (adult stages):
2.5 mg flubendazole (= 25 mg veterinary medicinal product) per kg body weight daily during 2 days, i.e. 2.5 g of the veterinary medicinal 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.

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

$$\frac{\text{mg veterinary medicinal product/kg body weight/day} \times \text{average body weight (kg) of animals to be treated}}{\text{average quantity of drinking water (l/animal) consumed in 4 h}} = \text{mg veterinary medicinal product per litre of drinking water}$$

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

9. Advice on correct administration

Administration in drinking water

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

Hens/chickens, 7 days of treatment

Total weight of chickens	Amount of medication to be used (g/ day)	Total amount of medication used (g/ 7 days)
1400 kg	20 g	7 x 20 g
3500 kg	50 g	7 x 50 g
7000 kg	100 g	7 x 100 g
52500 kg	750 g	7 x 750 g

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)
2000 kg	20 g	5 x 20 g
5000 kg	50 g	5 x 50 g
10000 kg	100 g	5 x 100 g
75000 kg	750 g	5 x 750 g

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)
800 kg	20 g	2 x 20 g
2000 kg	50 g	2 x 50 g
4000 kg	100 g	2 x 100 g
30000 kg	750 g	2 x 750 g

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

3) If less than entire package (a sachet or a container) is required, the required dose should be measured by suitably calibrated weighing equipment.

4) If the entire sachet is used, squeeze it gently before use and then empty the contents into the predilution recipient.

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 veterinary medicinal 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 veterinary medicinal 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.

10. Withdrawal periods

Pigs (meat and offal):
- dose 1 mg/kg body weight for 5 days: 3 days
- dose 2.5 mg/kg body weight for 2 days: 4 days

Chickens (meat and offal): 2 days
Eggs: zero days

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the packaging after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 6 months
Shelf life after first opening the sachet: Use immediately. Any suspension remaining in the sachet after first opening should be discarded.
Shelf life after dilution according to directions: 24 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription

14. Marketing authorisation numbers and pack sizes

Box containing 2 sachets (sachet PE/PET/aluminium/PET) of 20 g suspension for use in drinking water.
Box containing 24 sachets (sachet PE/PET/aluminium/PET) of 20 g suspension for use in drinking water.
Box containing 2 sachets (sachet PE/PET/aluminium/PET) of 50 g suspension for use in drinking water.
Box containing 24 sachets (sachet PE/PET/aluminium/PET) of 50 g suspension for use in drinking water.
Box containing 1 sachet (sachet PE/PET/aluminium/PET) of 100 g suspension for use in drinking water.
Box containing 5 sachets (sachet PE/PET/aluminium/PET) of 100 g suspension for use in drinking water.
Box containing 25 sachets (sachet PE/PET/aluminium/PET) of 100 g suspension for use in drinking water.
Box containing 4 containers (PP) with a closure (LDPE) of 750 g suspension for use in drinking water.

Not all pack sizes may be marketed.

Vm 01656/3063

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release <and contact details to report suspected adverse reactions>:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

<Local representatives <and contact details to report suspected adverse reactions>:>

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder. >

<17. Other information>

Approved 07 December 2023