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

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 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.

3. PHARMACEUTICAL FORM

Suspension for use in drinking water.

4. 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

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal:
chickens: 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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. 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.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4042

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABEL for box containing containers (4 x 750 g, 6 x 750 g)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 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.

3. PHARMACEUTICAL FORM

Suspension for use in drinking water.

4. PACKAGE SIZE

4 x 750 g
6 x 750 g

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal:
chickens: 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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf life after first opening the container: 6 months.

Shelf life after dilution according to directions: 24 hours.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4042

17. MANUFACTURER'S 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

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 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.

3. PHARMACEUTICAL FORM

Suspension for use in drinking water.

4. PACKAGE SIZE

20 g
50 g
100 g

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal:
chickens: 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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. 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.

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4042

17. MANUFACTURER'S BATCH NUMBER

Lot:

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

1 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.

3. PHARMACEUTICAL FORM

Suspension for use in drinking water.

4. PACKAGE SIZE

750 g

5. TARGET SPECIES

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Meat and offal:
chickens: 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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01656/4042

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
FLIMABEND 100 mg/g suspension for use in drinking water for chickens and pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
KRKA d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:
KRKA d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FLIMABEND 100 mg/g suspension for use in drinking water for chickens and pigs
Flubendazole.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 g of white to brownish white suspension 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.

4. INDICATION(S)

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. ADVERSE REACTIONS

No undesirable effects have been demonstrated with flubendazole after administration of the therapeutic dose in pigs.

In chickens, development disorders of the feathers cannot be fully excluded after the administration of flubendazole.

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 inform your veterinary surgeon.

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.
Hens/chickens:
1.43 mg flubendazole (= 14.3 mg product) per kg body weight daily 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):
1 mg flubendazole (= 10 mg product) per kg body weight daily 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):
2.5 mg flubendazole (= 25 mg product) per kg body weight daily 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:

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

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 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 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) 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 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.

10. WITHDRAWAL PERIOD(S)

Meat and offal:
chickens: 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

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.
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 WARNING(S)

Special warnings for each target species:
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.

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 product has been demonstrated in laying hens, pregnant and lactating sows. The product can be administered to these animals.

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

Overdose (symptoms, emergency procedures, antidotes), if necessary:
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.

User warnings:
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*.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Cardboard box containing 2 sachets (sachet PE/PET/aluminium/PET) of 20 g suspension for use in drinking water.
Cardboard box containing 24 sachets (sachet PE/PET/aluminium/PET) of 20 g suspension for use in drinking water.
Cardboard box containing 2 sachets (sachet PE/PET/aluminium/PET) of 50 g suspension for use in drinking water.
Cardboard box containing 24 sachets (sachet PE/PET/aluminium/PET) of 50 g suspension for use in drinking water.
Cardboard box containing 1 sachet (sachet PE/PET/aluminium/PET) of 100 g suspension for use in drinking water.
Cardboard box containing 5 sachets (sachet PE/PET/aluminium/PET) of 100 g suspension for use in drinking water.
Cardboard box containing 25 sachets (sachet PE/PET/aluminium/PET) of 100 g suspension for use in drinking water.
Cardboard box containing 4 containers (PP) with a closure (LDPE) of 750 g suspension for use in drinking water.
Cardboard box containing 6 containers (PP) with a closure (LDPE) of 750 g suspension for use in drinking water.

Not all pack sizes may be marketed.

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

Approved: 10/11/2017