*[Version 9.1,11/2024]*

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alphafluben 44 mg/ml oral gel for dogs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**
Flubendazole 44 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) | 1.8 mg |
| Propyl parahydroxybenzoate | 0.2 mg |
| Glycerol 85 percent (E422) | |
| Carbomer | |
| Sodium Hydroxide (for pH-adjustment) | |
| Purified water | |

White or almost white, odourless suspension gel.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs

### 3.2 Indications for use for each target species

Anthelmintic for the treatment of dogs infected with roundworms, hookworms and whipworms.
Roundworms: *Toxocara canis, Toxascaris leonina*
Hookworms: *Ancylostoma caninum*
Whipworms: *Trichuris vulpis*

### 3.3 Contraindications

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

### 3.4 Special warnings

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 or misadministration of the veterinary medicinal product

The decision to use the veterinary medicinal 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 individual animal.

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

Parasite resistance may develop to a particular class of anthelmintics after frequent and repeated administration of that anthelmintic class.

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

This veterinary medicinal product may cause allergic reactions. People with known hypersensitivity to flubendazole or to the excipients methyl parahydroxybenzoate and propyl parahydroxybenzoate should avoid contact with the veterinary medicinal product.

The veterinary medicinal product might be mildly irritant to eyes and skin. Avoid direct skin contact. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. If accidental eye or skin contact occurs, immediately rinse thoroughly with water.

The veterinary medicinal product should not be administered by pregnant women and women of child bearing age.

This veterinary medicinal product may be harmful when ingested, particularly for children. Avoid accidental ingestion of the veterinary medicinal product. Do not leave a syringe in the sight or reach of children. In order to prevent children from getting access to used syringes, keep the syringe in the original packaging after use. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Additional warnings when administering the product into the feed:
Avoid the access of children to the dog's medicated food. In order to prevent children from getting access to the dog's medicated food, pour it over a part of the feed and wait until the animal has completely consumed the medicated feed, then administer the rest of the feed. Give the treatment out of the sight and reach of children. Any uneaten medicated food must be removed immediately and the bowl washed thoroughly.
Wash hands when handling the product and cleaning the contaminated food bowl.

Special precautions for the protection of the environment:

Not applicable.

## 3.6 Adverse reactions

Dogs:

| | |
|---|---|
| Very rare<br>(<1 animal / 10 000 animals treated, including isolated reports): | Vomiting[1] |

[1] Transient

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 the package leaflet for respective contact details.

## 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in rats have shown evidence of teratogenic and fetotoxic effects at high doses. Use only

accordingly to the benefit/risk assessment by the responsible veterinarian.

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

None known.

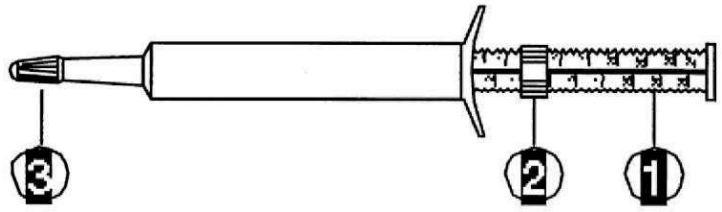
### 3.9 Administration routes and dosage

Recommended dose
22 mg flubendazole per kg bodyweight, one 7.5 ml syringe contains 330 mg flubendazole.

Administration
1 ml gel/2 kg bodyweight, once a day for three consecutive days.
One syringe is for a dog of up to 15 kg.

Administration route
The gel can be administered as follows:

- the exact dosage should be administered directly onto the tongue of the dog,
- the exact dosage should be mixed into the feed of the dog (recommended in case of aggressive dogs that are difficult to treat).




Remove the safety cap (3). Turn the ring (2) counterclockwise until it is at the mark on the dosing piston (1), which corresponds to the body weight of the animal in kg. Give the animal the dose. At the next treatment, add the animal's body weight to the number that the ring (2) was previously set to; then turn the ring to this new mark and administer the appropriate dose.
Example: For a dog of 3 kg body weight the ring for the first treatment is set to the 3 kg mark, of 6 kg body weight for the second and of 9 kg body weight for the third treatment.

Recommended treatment
Dogs:

- Puppies: at 1-2 weeks of age
- Young dogs (under 12 months of age): every 2-3 months
- Breeding bitches: during oestrous cycle, 10 days before and 10 days after parturition
- Adult dogs: every 3-4 months considering the local regulations
- All dogs: prior to vaccination

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

This veterinary medicinal product has a wide therapeutic margin. Five time overdose does not cause adverse reactions.

### 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

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QP52AC12

### 4.2 Pharmacodynamics

Flubendazole is a synthetic anthelmintic belonging to the benzimidazole carbamates. Flubendazole acts by binding to tubulin of the parasites' microtubules and blocking polymerization of tubulin molecules. These changes are relatively fast and are primarily seen in those target cells directly involved but in contrast the changes are not seen in the host cells. Flubendazole blocks cellular functions, reducing absorption and digestion of nutrients in the intestinal tract of the parasite, with accumulation of protein-digesting enzymes resulting in death of the parasite. Flubendazole also inhibits the egg production and oviposition of parasites.

### 4.3 Pharmacokinetics

Flubendazole is poorly absorbed from the gastrointestinal tract. This is reflected by a high faecal excretion of unchanged parent drug. The very small fraction absorbed is extensively metabolised in the liver, involving hydrolysis and reduction. The biotransformation products are conjugated to glucuronides or sulphate conjugates and excreted in the bile and the urine in small quantities. The excretion in urine is relatively low and consists almost exclusively of metabolites, with only small amounts of unchanged compound.

The maximum plasma concentrations of unchanged substance after oral administration of 10 mg/kg of radiolabeled flubendazole in dogs were less than 10 ng/ml. The plasma half-life of flubendazole and its metabolites is 16 hours. After oral administration of the veterinary medicinal product at a dose of 22 mg/kg body weight, the maximum plasma concentrations were approximately 5 ng/ml.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

None known.

### 5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 90 days.

### 5.3. Special precautions for storage

Store below 25°C.
Do not refrigerate or freeze.

### 5.4 Nature and composition of immediate packaging

7.5 ml gel in a linear low-density polyethylene (LLDPE) plastic oral syringe, with polystyrene plunger packaged in carton.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

ALPHAVET Zrt.

## 7. MARKETING AUTHORISATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{DD month YYYY}

## 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 (https://medicines.health.europa.eu/veterinary).

**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alphafluben 44 mg/ml oral gel

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

**Active substance:**
Flubendazole 44 mg

## 3. PACKAGE SIZE

7.5 ml

## 4. TARGET SPECIES

Dogs

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp: {mm/yyyy}
Once opened use within 90 days.
Once opened, use by……

## 9. SPECIAL STORAGE PRECAUTIONS

Store below 25°C.
Do not refrigerate or freeze.

## 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

ALPHAVET Zrt.

## 14. MARKETING AUTHORISATION NUMBERS

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Label**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alphafluben

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Flubendazole 44 mg/ml

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp: {mm/yyyy}
Once opened use within 90 days.
Once opened, use by……

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Alphafluben 44 mg/ml oral gel for dogs

## 2. Composition

Each ml contains:
**Active substance:**
Flubendazole 44 mg

**Excipients:**
Methyl parahydroxybenzoate (E218) 1.8 mg
Propyl parahydroxybenzoate 0.2 mg

White or almost white, odourless suspension gel.

## 3. Target species

Dogs

## 4. Indications for use

Anthelmintic for the treatment of dogs infected with roundworms, hookworms and whipworms.
Roundworms: *Toxocara canis, Toxascaris leonina*
Hookworms: *Ancylostoma caninum*
Whipworms: *Trichuris vulpis*

## 5. Contraindications

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

## 6. Special warnings

Special warnings:

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 or misadministration of the veterinary medicinal product

The decision to use the veterinary medicinal 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 individual animal

Special precautions for safe use in the target species:

Parasite resistance may develop to a particular class of anthelmintics after frequent and repeated administration of that anthelmintic class.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may cause allergic reactions. People with known hypersensitivity to flubendazole or to the excipients methyl parahydroxybenzoate and propyl parahydroxybenzoate should avoid contact with the veterinary medicinal product.

The veterinary medicinal product might be mildly irritant to eyes and skin. Avoid direct skin contact. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. If accidental eye or skin contact occurs, immediately rinse thoroughly with water.

The veterinary medicinal product should not be administered by pregnant women and women of child bearing age.

This veterinary medicinal product may be harmful when ingested, particularly for children. Avoid accidental ingestion of the veterinary medicinal product. Do not leave a syringe in the sight or reach of children. In order to prevent children from getting access to used syringes, keep the syringe in the original packaging after use. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Additional warnings when administering the product into the feed:
Avoid the access of children to the dog's medicated food. In order to prevent children from getting access to the dog's medicated food, pour it over a part of the feed and wait until the animal has completely consumed the medicated feed, then administer the rest of the feed. Give the treatment out of the sight and reach of children. Any uneaten medicated food must be removed immediately and the bowl washed thoroughly. Wash hands when handling the product and cleaning the contaminated food bowl.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
Laboratory studies in rats have shown evidence of teratogenic and fetotoxic effects at high doses.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Overdose (symptoms, emergency procedures, antidotes):
This veterinary medicinal product has a wide therapeutic margin. Five-time overdose does not cause adverse reactions.

## 7. Adverse events

Dogs:

| | |
|---|---|
| Very rare<br>(<1 animal / 10 000 animals treated, including isolated reports): | Vomiting[1] |

[1]Transient

Reporting adverse events is important. It allows continuous safety monitoring of a 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 its local representative 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

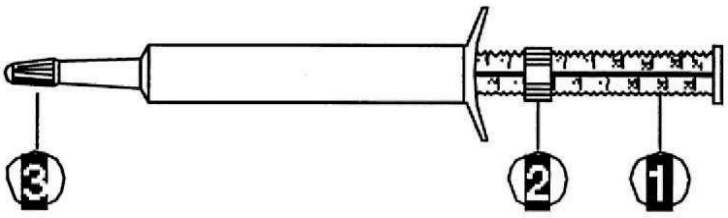
Recommended dose
22 mg flubendazole per kg bodyweight, one 7.5 ml syringe contains 330 mg flubendazole.

Administration
1 ml gel/2 kg bodyweight, once a day for three consecutive days.
One syringe is for a dog of up to 15 kg.

Administration route
The gel can be administered as follows:

- the exact dosage should be administered directly onto the tongue of the dog,
- the exact dosage should be mixed into the feed of the dog (recommended in case of aggressive dogs that are difficult to treat).

## 9. Advice on correct administration

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Recommended treatment
Dogs:
- Puppies: at 1-2 weeks of age
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- Breeding bitches: during oestrous cycle, 10 days before and 10 days after parturition
- Adult dogs: every 3-4 months considering the local regulations
- All dogs: prior to vaccination

To ensure a correct dosage, body weight should be determined as accurately as possible.

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.
Store below 25°C.
Do not refrigerate or freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 90 days.

## 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

7.5 ml gel in a linear low-density polyethylene (LLDPE) plastic oral syringe, with polystyrene plunger packaged in carton.

## 15. Date on which the package leaflet was last revised

{DD month YYYY}

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 contact details to report suspected adverse events:
ALPHAVET Zrt., Hofherr Albert utca 42., H-1194 Budapest, Hungary
Tel: +36 22 534 500
E-mail: alpha-vet@alpha-vet.hu

Manufacturer responsible for batch release:
ALPHAVET Zrt., Bábolna, Köves János utca 13, H-2943 Bábolna, Hungary

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

## 17. Other information