LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTPRO 68 mg chewable tablets for dogs >10–25 kg

afoxolaner

2. STATEMENT OF ACTIVE SUBSTANCES

68 mg afoxolaner

3. PHARMACEUTICAL FORM

Chewable tablets

4. PACKAGE SIZE

1 chewable tablet
3 chewable tablets
6 chewable tablets

5. TARGET SPECIES

Dogs >10–25 kg

6. INDICATION(S)

Kills fleas and ticks
Effective for at least 5 weeks against fleas and up to one month against ticks

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Activity of the product is not affected if treated dogs are exposed to water.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Keep the blister in the outer carton.

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.

NFA-VPS

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

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5012

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTPRO 68 mg dogs >10–25 kg

afoxolaner

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica Gmbh

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
FRONTPRO 68 mg chewable tablets for dogs >10–25 kg

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

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
GERMANY

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4 Chemin du Calquet
31000 Toulouse
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTPRO 68 mg chewable tablets for dogs (>10–25 kg)
afoxolaner

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

Each chewable tablet contains:

FRONTPRO	Afoxolaner (mg)
chewable tablets for dogs 2–4 kg	11.3
chewable tablets for dogs >4–10 kg	28.3
chewable tablets for dogs >10–25 kg	68
chewable tablets for dogs >25–50 kg	136

Mottled red to reddish brown, circular shaped (tablets for dogs 2–4 kg), or rectangular shaped (tablets for dogs >4–10 kg, tablets for dogs >10–25 kg and tablets for dogs >25–50 kg).

4. INDICATIONS

Treatment of flea infestation in dogs (*Ctenocephalides felis* and *C. canis*) One treatment provides immediate and persistent flea killing activity for 5 weeks. The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD) where this has been previously diagnosed by a veterinarian.

Treatment of tick infestation in dogs (*Dermacentor reticulatus, Ixodes ricinus, Rhipicephalus sanguineus).* One treatment provides immediate and persistent tick killing activity for one month.

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Mild gastrointestinal effects (vomiting, diarrhoea), pruritus [itching], lethargy, anorexia [not eating], and neurological signs (convulsions, ataxia [loss of coordination] and muscle tremors) have been reported very rarely. Most reported adverse reactions were self-limiting and of short duration.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)).
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Dogs

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

For oral use

Dosage:
The product should be administered in accordance with the following table to ensure a dose of 2.7-7 mg/kg bodyweight.

Bodyweight of dog (kg)	**Strength and number of chewable tablets to be administered**			
	FRONTPRO 11 mg	FRONTPRO 28 mg	FRONTPRO 68 mg	FRONTPRO 136 mg
2–4	1			
>4–10		1		
>10–25			1	
>25–50				1

For dogs above 50 kg bodyweight, use an appropriate combination of chewable tablets of different/same strengths.
The tablets should not be divided.

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 before use.

Treatment schedule:

Treatment of flea and tick infestations:
For optimal control of flea and tick infestations, the product should be administered at monthly intervals throughout the flea and/or tick seasons, based on local epidemiological situations and the animal's lifestyle.

9. ADVICE ON CORRECT ADMINISTRATION

FRONTPRO tablets are chewable, beef flavoured and palatable to most dogs. If the dog does not accept the tablets directly they may be administered with food.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
This veterinary medicinal product does not require any special storage conditions.

12. SPECIAL WARNINGS

Special warnings for each target species:
Unnecessary use of antiparasitics or use deviating from the instructions provided 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 infestation based on its epidemiological features, for each individual animal.

Parasites need to start feeding on the host to become exposed to afoxolaner; therefore the risk of the transmission of parasite borne diseases cannot be excluded.

When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time.

All stages of fleas can infest the dog’s bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning

of the control measures, these areas should be treated with a suitable environmental product and then vacuumed regularly.

Special precautions for use in animals:
In the absence of available data, a veterinary surgeon should be consulted before treatment of puppies less than 8 weeks of age and/or dogs less than 2 kg bodyweight.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may be harmful following ingestion.
To prevent children from getting access to the veterinary medicinal product, remove only one chewable tablet at a time from the blister. Return the blister with the remaining chewable tablets into the carton

Wash hands after handling the product.

Other precautions
The active substance is mostly excreted in the faeces (poo) and may be toxic to non-target organisms. To avoid contamination of the environment, ensure that dog faeces are bagged up and disposed of safely.

Pregnancy and lactation:
Can be used in breeding, pregnant and lactating female dogs.
The safety of the veterinary medicinal product has not been established in breeding males.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects, or any adverse effect on the reproductive capacity of males.

Consult a veterinary surgeon before treatment of breeding males.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions were observed in healthy Beagle puppies over 8 weeks of age when treated with 5 times the maximum dose repeated 6 times at intervals of 2-4 weeks.

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

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.
The product should not enter water courses as it may be dangerous for fish and other aquatic organisms.
Ask your veterinary surgeon how to dispose of medicines no longer required.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

Afoxolaner is an insecticide and acaricide belonging to the isoxazoline family.

FRONTPRO is active against adult fleas as well as several tick species such as *Dermacentor reticulatus* and *D. variabilis, Ixodes ricinus* and *I. scapularis, Rhipicephalus sanguineus, Amblyomma americanum,* and *Haemaphysalis longicornis.*

FRONTPRO kills fleas within 8 hours and ticks within 48 hours.

The product kills fleas before egg production and therefore prevents household contamination.
Activity of the product is not affected if treated dogs are exposed to water.

For each strength, the chewable tablets are available in the following pack sizes:
Carton with 1 blister of 1, 3 or 6 chewable tablets

Not all pack sizes may be marketed.

NFA-VPS

Vm 04491/5009
Vm 04491/5010
Vm 04491/5011
Vm 04491/5012

Approved 18 November 2024
Gavin Hall