ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTPRO 11 mg chewable tablets for dogs 2–4 kg
FRONTPRO 28 mg chewable tablets for dogs >4–10 kg
FRONTPRO 68 mg chewable tablets for dogs >10–25 kg
FRONTPRO 136 mg chewable tablets for dogs >25–50 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

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

Excipients:

Qualitative composition of excipients and other constituents
Maize starch
Soy protein fines
Braised beef flavouring
Povidone (E1201)
Macrogol 400
Macrogol 4000
Macrogol 15 hydroxystearate
Glycerol (E422)
Medium-chain triglycerides

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of flea infestation in dogs (*Ctenocephalides felis* and *C. canis*).
One treatment provides immediate and persistent flea killing activity for 5 weeks.

Treatment of tick infestation in dogs (*Dermacentor reticulatus, Ixodes ricinus, Ixodes hexagonus, 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.

3.3 Contraindications

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

3.4 Special warnings

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.

The possibility that other animals in the same household can be a source of re-infestation with fleas and/or ticks should be considered, and these should be treated as necessary with an appropriate product.

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.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In the absence of available data, use only according to the benefit-risk assessment by the responsible veterinarian in puppies less than 8 weeks of age and/or dogs less than 2 kg body weight.

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

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 cardboard box. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Neurological signs: convulsions[1], ataxia[1] and muscle tremors[1]. Skin and appendage disorders[1]: pruritus. Systemic disorders[1]: lethargy, anorexia. Digestive tract disorders[2]: vomiting[1], diarrhoea[1].

[1] Most reported adverse events were self-limiting and of short duration.
[2] Usually mild.

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:
Can be used in pregnant and lactating female dogs.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.

Fertility:
Can be used in breeding female dogs.
The safety of the veterinary medicinal product has not been established in breeding male dogs, use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and rabbits have not produced any evidence of any adverse effect on the reproductive capacity of males.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

For oral use.

Dosage:
To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.

The product should be administered at a dose of 2.7–7 mg/kg body weight in accordance with the following table:

Body weight 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
>50	use an appropriate combination of chewable tablets of different/same strengths.			

The chewable tablets should not be divided.

Method of administration:
The tablets are chewable and palatable to most dogs. If the dog does not accept the tablets directly, they may be administered with food.

Treatment schedule:
For optimal control of flea and tick infestation, the product should be administered at monthly intervals throughout the flea and/or tick seasons. The need for and frequency of re-treatment(s) should take into account the local epidemiological situation and the animal's lifestyle.

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

No adverse events 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.

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: QP53BE01.

4.2 Pharmacodynamics

Afoxolaner is an insecticide and acaricide belonging to the isoxazoline family. Afoxolaner acts at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarines. The selective toxicity of afoxolaner between insect/acarines and mammals may be inferred by the differential sensitivity of the insect/acarines' GABA receptors versus mammalian receptors.

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

The veterinary medicinal product kills fleas within 8 hours and ticks within 48 hours.

The veterinary medicinal product kills fleas before egg production and therefore prevents household contamination.

4.3 Pharmacokinetics

After oral administration in dogs, afoxolaner was shown to have high systemic absorption following administration. The absolute bioavailability was 74%. The mean maximum concentration (C_{max}) was 1,655 ± 332 ng/ml in plasma at 2–4 hours (T_{max}) after a 2.5 mg/kg afoxolaner dose.

Afoxolaner distributes into tissues with a volume of distribution of 2.6 ± 0.6 l/kg and a systemic clearance value of 5.0 ± 1.2 ml/hr/kg. The terminal plasma half-life is approximately 2 weeks in most dogs; however, half-life of afoxolaner can differ between dogs (e.g. in one study, $t_{½}$ in Collies at 25 mg/kg body weight was up to 47.7 days) with no effect on safety. *In vitro* experiments demonstrated that P-glycoprotein efflux does not occur, confirming that afoxolaner is not a substrate for the P-glycoprotein transporters.

Afoxolaner in the dog is metabolised to more hydrophilic compounds and then eliminated. The metabolites and parent compound are eliminated from the body via urinary and biliary excretion with the majority eliminated in the bile. No evidence of enterohepatic recycling has been observed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is individually packaged in thermoformed laminated PVC blisters with paper-backed aluminium (Aclar/PVC/Alu).

One cardboard box contains one blister of 1, 3 or 6 chewable tablets.

Not all pack sizes may be marketed.

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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/19/240/001–003
EU/2/19/240/005–007
EU/2/19/240/009–011
EU/2/19/240/013–015

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 20/05/2019

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

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

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTPRO 11 mg chewable tablets
FRONTPRO 28 mg chewable tablets
FRONTPRO 68 mg chewable tablets
FRONTPRO 136 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:

11.3 mg afoxolaner
28.3 mg afoxolaner
68 mg afoxolaner
136 mg afoxolaner

2–4 kg
>4–10 kg
>10–25 kg
>25–50 kg

3. PACKAGE SIZE

1 chewable tablet
3 chewable tablets
6 chewable tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

Kills fleas and ticks.
Effective for 30 days.

6. ROUTES OF ADMINISTRATION

Oral use.
Administer with or without food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/19/240/001 (1 x 11.3 mg)
EU/2/19/240/002 (3 x 11.3 mg)
EU/2/19/240/003 (6 x 11.3 mg)
EU/2/19/240/005 (1 x 28.3 mg)
EU/2/19/240/006 (3 x 28.3 mg)
EU/2/19/240/007 (6 x 28.3 mg)
EU/2/19/240/009 (1 x 68.0 mg)
EU/2/19/240/010 (3 x 68.0 mg)
EU/2/19/240/011 (6 x 68.0 mg)
EU/2/19/240/013 (1 x 136 mg)
EU/2/19/240/014 (3 x 136 mg)
EU/2/19/240/015 (6 x 136 mg)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTPRO

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

11.3 mg afoxolaner
28.3 mg afoxolaner
68 mg afoxolaner
136 mg afoxolaner

2–4 kg
>4–10 kg
>10–25 kg
>25–50 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

FRONTPRO 11 mg chewable tablets for dogs 2–4 kg
FRONTPRO 28 mg chewable tablets for dogs >4–10 kg
FRONTPRO 68 mg chewable tablets for dogs >10–25 kg
FRONTPRO 136 mg chewable tablets for dogs >25–50 kg

2. Composition

Each chewable tablet contains:

Active substance:

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 chewable tablets (for dogs 2–4 kg) or rectangular shaped chewable tablets (for dogs >4–10 kg, for dogs >10–25 kg and for dogs >25–50 kg).

3. Target species

Dogs.

4. Indications for use

Treatment of flea infestation in dogs (*Ctenocephalides felis* and *C. canis*).
One treatment provides immediate and persistent flea killing activity for 5 weeks.

Treatment of tick infestation in dogs (*Dermacentor reticulatus, Ixodes ricinus, Ixodes hexagonus, 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. Special warnings

Special warnings:
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.

The possibility that other animals in the same household can be a source of re-infestation with fleas and/or ticks should be considered, and these should be treated as necessary with an appropriate product.

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.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC 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.

Special precautions for safe use in the target species:
In the absence of available data, use only according to the benefit-risk assessment by the responsible veterinarian in puppies less than 8 weeks of age and/or dogs less than 2 kg body weight.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 cardboard box. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after handling the veterinary medicinal product.

Pregnancy and lactation:
Can be used in pregnant and lactating female dogs.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.

Fertility:
Can be used in breeding female dogs.
The safety of the veterinary medicinal product has not been established in breeding male dogs, use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and rabbits have not produced any evidence of any adverse effect on the reproductive capacity of males.

Overdose:
No adverse events 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.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Neurological signs: convulsions[1], ataxia[1] (lack of coordination) and muscle tremors[1].
Skin and appendage disorders[1]: pruritus (itching).
Systemic disorders[1]: lethargy (decreased activity), anorexia (appetite loss).
Digestive tract disorders[2]: vomiting[1], diarrhoea[1].

[1] Most reported adverse events were self-limiting and of short duration.
[2] Usually mild.

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 the local representative of 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

For oral use.

Dosage:
To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.

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

Body weight 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
>50	use an appropriate combination of chewable tablets of different/same strengths.			

The chewable tablets should not be divided.

Treatment schedule:
For optimal control of flea and tick infestation, the product should be administered at monthly intervals throughout the flea and/or tick seasons. The need for and frequency of re-treatment(s) should take into account the local epidemiological situation and the animal's lifestyle.

9. Advice on correct administration

The tablets are chewable, beef flavoured and palatable (tasty) to most dogs. The veterinary medicinal product can be administered with or without food: if the dog does not accept the tablets directly, they may be administered with food.

10. Withdrawal periods

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 cardboard box and blister 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 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 not subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/19/240/001–003
EU/2/19/240/005–007
EU/2/19/240/009–011
EU/2/19/240/013–015

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/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:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

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

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.

België/Belgique/Belgien
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17. Other information

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

FRONTPRO is active against adult fleas and several tick species such as *Dermacentor reticulatus* and *D. variabilis, Ixodes ricinus, I. hexagonus* 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.