SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FRONTPRO 28 mg chewable tablets for dogs >4–10 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:
Afoxolaner: 28.3 mg

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, rectangular shaped chewable tablets

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. The veterinary medicinal 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, Ixodes hexagonus,*and *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

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 veterinary medicinal 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.

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 animals should be treated as necessary 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.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

In the absence of available data, a veterinary surgeon should be consulted before commencing 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 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:
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.

Other precautions:
Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Neurological disorders (convulsions[1], ataxia[1] and muscle tremors[1]). Pruritus[1]. Lethargy[1], anorexia[1]. 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 males. In breeding males, a veterinary surgeon should be consulted before commencing treatment.
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:
The veterinary medicinal product should be administered at a dose of 2.7–7 mg/kg bodyweight in accordance with the following table:

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 chewable 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.

Method of 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.

Treatment schedule:
Treatment of flea and tick infestations:
For optimal control of flea and tick infestations, the veterinary medicinal 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 ATC vet 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.*

FRONTPRO 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 Pharmacokinetic particulars

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 bodyweight 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).

Cardboard box with 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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.
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 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 61700/5044

8. DATE OF FIRST AUTHORISATION

20 May 2019

9. DATE OF REVISION OF THE TEXT

January 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

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

Gavin Hall
Approved: 29 May 2026