1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fleaway Plus 67 mg/60.3 mg spot-on solution for small dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 0.67 ml contains:

Active substances:

Fipronil	67.00 mg
(S)-methoprene	60.30 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E320)	0.13 mg
Butylhydroxytoluene (E321)	0.07 mg
Ethanol, anhydrous	
Polysorbate 80	
Povidone K17	
Diethylene glycol monoethyl ether	

Clear amber solution.

3. CLINICAL PARTICULARS

3.1 Target Species

Dogs (≥ 2 – 10 kg)

3.2 Indications for use for each target species

For the treatment of dogs weighing 2 to 10 kg bodyweight:
- To be used against infestations with fleas, alone or in association with ticks and/or biting lice.
- Kills fleas (*Ctenocephalides* spp.) on treated dogs for up to 8 weeks and prevents eggs, larvae and pupae from exposed fleas from developing for up to 8 weeks.
- Kills ticks (*Ixodes ricinus*, *Dermacentor variabilis*, *Dermacentor reticulatus*, *Rhipicephalus sanguineus*) on treated dogs for up to 4 weeks.
- Treatment of infestations with biting lice (*Trichodectes canis*).

3.3 Contraindications

In the absence of available data, the product should not be used on puppies less than 8 weeks old and/or weighing less than 2 kg.

Do not use on sick (e.g. systemic diseases, fever) or convalescent animals.
Do not use in rabbits, as adverse reactions with even mortality could occur.
In absence of studies, the use of the product is not recommended in non-target species.
This product is specifically developed for dogs. Do not use in cats and ferrets, as this could lead to overdosing.

3.4 Special warnings

Bathing/immersion in water within 2 days after application of the product and more frequent bathing than once a week should be avoided, as no study has been performed to investigate how this affects the efficacy of the product. Emollient shampoos can be used prior to treatment, but reduce the duration of protection against fleas to approximately 5 weeks when used weekly after application of the product. Weekly bathing with a 2% chlorhexidine medicated shampoo did not affect efficacy against fleas during a 6 week long study.
Dogs should not be allowed to swim in watercourses for 2 days after application (see section 5.5).
There may be an attachment of a few ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.
Fleas from pets often infest the animal's basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in case of massive infestation and at the beginning of the control measures, with a suitable insecticide and 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 based on its epidemiological features, for each individual animal.

In the absence of risk of co-infection, a narrow spectrum product should be used.
The possibility that other animals in the same household can be a source of re-infection with fleas and lice should be considered, and these should be treated as necessary with an appropriate product.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid contact with the animal's eyes.
It is important to make sure that the product is applied to an area where the animal cannot lick it off and to make sure that animals do not lick each other following treatment.

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

This product can cause mucous membrane, skin and eye irritation. Therefore, contact of the product with mouth, skin and eyes should be avoided.
Animals or operators with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with the veterinary medicinal product. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water.
After accidental ocular exposure the eye should be rinsed carefully with pure water.
Wash hands after use.
Treated animals should not be handled until the application site is dry, and children should not be allowed to play with treated animals until the application site is dry. It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.
Do not smoke, drink or eat during application.

Special precautions for the protection of the environment:

Fipronil and (S)-methoprene should not enter water courses as this may be dangerous for fish and other aquatic organisms. Spillage of product should be avoided where possible and pets should not be bathed/shampooed or allowed to swim in water courses within 2 days after application of the product to avoid environmental contamination.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reactions (skin discoloration[1], hair loss[1], itching[1], reddening[1]). Generalised itching or hair loss. Hypersalivation[2], vomiting, respiratory signs. Increased sensitivity to stimulation[3], depression[3], other nervous signs[3].

1 Transient.
2 If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
3 Reversible.

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. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

The product can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

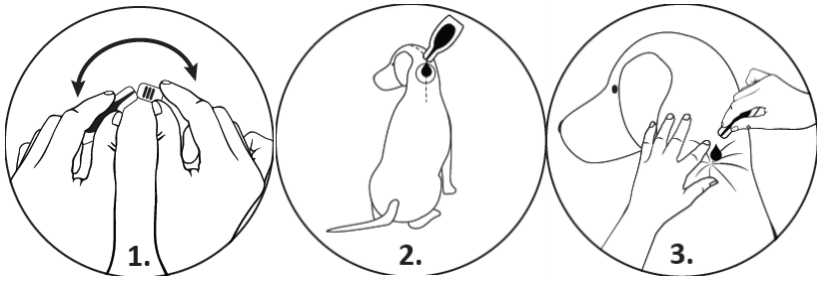
None known.

3.9 Administration routes and dosage

Spot-on use.
In dogs, the minimum recommended dose is 6.7 mg fipronil / kg bw and 6 mg (S)methoprene / kg bw, by topical application to the skin, equivalent to one pipette of 0.67 mL for one animal weighing over 2kg and up to 10kg.
The minimum treatment interval is 4 weeks.

How to use this product

1. Hold the pipette in an upright position.
2. Tap the narrow part of the pipette to ensure the contents remain within the main body of the pipette.
3. Snap back the tip.
4. Part the coat on the back of the animal at the base of the neck in front of the shoulder blades until the skin is visible.
5. Place the tip of the pipette on the skin and squeeze the pipette several times to empty its contents completely and directly onto the skin in one spot.



Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

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

No adverse effects were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of experiencing adverse effects (see section 3.6) may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

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 PARTICULARS

4.1 ATCvet code:

QP53AX65

4.2 Pharmacodynamics

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by interacting with 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. Fipronil kills fleas within 24 hours and ticks (*Dermacentor reticulatus, Dermacentor variabilis, Rhipicephalus sanguineus, Ixodes scapularis, Ixodes ricinus, Haemaphysalis*

longicornis, Haemaphysalis flava, Haemaphysalis campanulata) and lice within 48 hours post-exposure.

(S)-Methoprene is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues that inhibit the development of immature stages of insects. This compound mimics the action of juvenile hormone and causes impaired development and death of the developing stages of fleas. The on-animal ovicidal activity of (S)- methoprene results from either direct penetration of the eggshell of newly laid eggs or from absorption through the cuticle of the adult fleas. (S)-methoprene is also effective in preventing flea larvae and pupae from developing, which prevents contamination of the environment of treated animals with the immature stages of fleas.

4.3 Pharmacokinetics

Studies of metabolism of fipronil have demonstrated that the major metabolite is the sulfone derivative of fipronil. (S)-methoprene is extensively degraded into carbon dioxide and acetate that are subsequently incorporated into endogenous materials.

The pharmacokinetic profiles after topical application of fipronil and (S)-methoprene in combination were studied in dogs in comparison to intravenous dosing of fipronil or (S)-methoprene alone. This established absorption and other pharmacokinetic parameters. The topical application resulted in low systemic absorption of fipronil (11%) with a mean maximum concentration (C_{max}) of approximately 35 ng/ml fipronil and 55 ng/ml of fipronil sulfone in plasma.

Peak fipronil plasma concentrations are slowly attained (mean t_{max} approximately 101 h), and decline slowly (mean terminal half-life approximately 154 h, highest values are observed for males). Fipronil is extensively metabolised to fipronil sulfone after topical administration.
Plasma concentrations of (S)-methoprene were below the limit of quantitation (20 ng/ml) in dogs after topical application.

Both (S)-methoprene and fipronil, together with its major metabolite, are well-distributed in the haircoat of a dog within one day after application. The concentrations of fipronil, fipronil sulfone and (S)-methoprene in the hair coat decrease with time and are detectable for at least 60 days after dosing. Parasites are killed through contact rather than systemic exposure.
No pharmacological interaction between fipronil and (S)-methoprene was noted.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

Store in the original package in order to protect from light.

5.4 Nature and composition of immediate packaging

A white pipette composed of a heat-formed shell of polypropylene/cyclic olefin copolymer/polypropylene layer and polyethylene/ethylene vinyl alcohol/polyethylene layer.

Box with 1, 2, 3 or 4, pipettes in individual foil sachets.
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.

The veterinary medicinal product should not enter water courses as fipronil and (S)-methoprene may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/106/005

8. DATE OF FIRST AUTHORISATION

10/01/2020

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

26/02/2025

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