

For the use of Registered Veterinary Practitioner, Hospital or Laboratory

FIPROFORT® PLUS

(Fipronil and (S)-methoprene Spot-on Solution for cats and dogs)

Each pipette of 0.67ml of **FIPROFORT® PLUS for Dogs upto 10kg** contains

Fipronil	9.8 % w/v
(S)-methoprene	8.8% w/v
Excipients	q.s.

Each pipette of 1.34ml of **FIPROFORT® PLUS for Dogs over 10kg upto 20kg** contains

Fipronil	9.8 % w/v
(S)-methoprene	8.8% w/v
Excipients	q.s.

Each pipette of 2.68 ml of **FIPROFORT® PLUS for Dogs over 20kg upto 40kg** contains

Fipronil	9.8 % w/v
(S)-methoprene	8.8% w/v
Excipients	q.s.

Each pipette of 4.02 ml of **FIPROFORT® PLUS for Dogs over 40kg upto 60kg** contains

Fipronil	9.8 % w/v
(S)-methoprene	8.8% w/v
Excipients	q.s.

Each pipette of 0.50ml **FIPROFORT® PLUS for Cats and Kittens 8 weeks or older** contains

Fipronil	9.8 % w/v
(S)-methoprene	11.8% w/v
Excipients	q.s.

Category: Insecticide-acaricide

Pharmacodynamics:

Fipronil is belonging to the family phenylpyrazole. It acts by interaction with complexes formed between the chloride channels and their ligands, especially the neurotransmitter GABA (gamma-amino butyric acid), thus blocking the transfer of chloride ions across cell membranes to levels pre and post synaptic. It thus causes uncontrolled activity on the central nervous system of insects and mites and causes their death. Fipronil kills fleas within 24 hours, ticks (*Dermacentor variabilis*, *Rhipicephalus sanguineus*, *Ixodes scapularis*, *Ixodes ricinus*, *Haemaphysalis longicornis*, *Haemaphysalis flava* and *Haemaphysalis campanulata*) and lice within 48 hours after application of the product.

The (S)-methoprene is a regulator of insect growth (ROI) of the class of similar juvenile hormone, it inhibits the development of immature stages of

insects. Mimicking the action of the juvenile hormone, the compound causes impaired development and death of immature stages of fleas. The ovicidal activity of (S)-methoprene applied to the cat results either from direct penetration into the shell flea eggs newly laid or its absorption through the cuticle of adult fleas. The (S)-methoprene is also effective in preventing the development of larvae and pupae chip, prevents contamination of the habitat of cats treated with the immature stages of fleas.

Pharmacokinetics:

Pharmacokinetic studies have been reported for topical administration of fipronil and (S)-methoprene in association, in cats in comparison with those of each active ingredient administered separately intravenously. In cats, after administration of the association topically with oral exposure potential by licking, fipronil has an absolute bioavailability (18%) with a mean plasma concentration maximum of approximately 100 ng/ml for fipronil and 13 ng/ml for fipronil sulfone.

In cats, the plasma concentrations of fipronil rapidly reach a peak average of about 6 hours and decreases with a half-life by approximately 25 hours. Fipronil is poorly metabolized by fipronil sulfone in cats. Fipronil and its main metabolite and the (S)-methoprene spread widely in the cat's coat the day after application.

Plasma concentrations of (S)-methoprene are generally below the quantification (20 ng/ml) in cats after topical administration.

The concentrations of fipronil, fipronil sulfone and (S)-methoprene in peeling decreases with time, but are detectable at least 59 days after application in cats. Parasites are killed mainly by contact and not by systemic exposure. No pharmacological interference between fipronil and (S)-methoprene was detected.

Indications and Dosage:**FIPROFORT® PLUS for dogs****Fleas**

- Kills Fleas, flea eggs and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Management of existing infestation and prevention of new infestation
- Kills fleas that may cause flea allergy dermatitis

Ticks

- Kills all life stages of ticks (larvae, nymph, and adult), including Brown Dog Tick (*Rhipicephalus sanguineus*), American Dog Tick (*Dermacentor variabilis*), Lone star Tick (*Amblyomma americanum*), and Deer Tick (*Ixodes scapularis*)
- Kills ticks that may transmit Babesiosis, Ehrlichiosis, Anaplasmosis and other tick-borne diseases

Lice

- Rapidly eliminates chewing lice infestations

Mites

- Aids in control of sarcoptic mange infestations

FIPROFORT® PLUS for Cats & Kittens**Fleas**

- Kills Fleas, flea eggs and flea larvae
- Prevents all flea stages (eggs, larvae, pupae) from developing
- Management of existing infestation and prevention of new infestation
- Kills fleas that may cause flea allergy dermatitis

Ticks

- Kills all life stages of ticks (larvae, nymph, and adult), including Brown Dog Tick (*Rhipicephalus sanguineus*), American Dog Tick (*Dermacentor variabilis*), Lone star Tick (*Amblyomma americanum*), and Deer Tick (*Ixodes scapularis*)
- Kills ticks that may transmit Babesiosis, Ehrlichiosis, Anaplasmosis and other tick-borne diseases

Lice

- Rapidly eliminates chewing lice infestations

Recommended Dosage is as below:

Weight (kg)	Dose
Dogs upto 10 kg	0.67 ml pipette
Dogs over 10 kg upto 20 kg	1.34 ml pipette
Dogs over 20 kg upto 40 kg	2.68 ml pipette
Dogs over 40 upto 60 kg	4.02 ml pipette
Dogs over 60 kg	Two pipettes of 2.68 ml
Cats and Kittens 8 weeks or older	0.5ml pipette

Treatment Frequency:

For Fleas: Monthly application is recommended for cats and dogs. All animals in a household should be treated at the same time. It is especially important to treat all household animals if any pet is allergic to fleas (flea allergy dermatitis).

Paralysis Ticks: Once monthly application in cats and dogs is recommended.

Biting Lice: Treat all household cats and dogs at the same time.

Application:

Break the snap-off top from the pipette along the scored line. Part the hair at back of cat, at the base of the neck between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze gently at one or two spots to empty its contents onto the skin. Care should be taken to avoid excessive wetting of hair during treatment of cats. Do not allow treated cats to lick each other or rub against other animals until the application site is dry.

Caution: Hazardous to Human.

This product may cause irritation of mucous membranes, skin and eyes. So avoid contact of the product with the mouth, skin or eyes. Cats or those who have known hypersensitivity to insecticides or alcohol should avoid contact with the drug. Avoid contact of contents with the fingers. If this occurs, wash hands with soap and water. In case of accidental exposure with eyes, rinse with clean water carefully. Do not handle treated cats and don't allow children to play with treated cats until the application site is dry. It is therefore recommended that cats are not treated in the day but in the early evening and that recently treated cats are not allowed to sleep with owners, especially children. Do not smoke, drink or eat during application.

Water fastness:

Cats and dogs may be treated with FIPROFORT® PLUS following bathing and shampooing ones they are dry. The product will spread over the coat of animal within 24 hours. Once spread, FIPROFORT® PLUS is water fast. Thereafter, bathing, water immersion or exposure to sunlight will not reduce the efficacy of FIPROFORT® PLUS.

Contraindications and Warnings:

- FIPROFORT® PLUS is for external application only.
- Do not use FIPROFORT® PLUS if you or your pet has a known hypersensitivity to insecticides or alcohol. When using on dogs, dogs should be weighed accurately prior to treatment.
- Do not use in rabbits, as adverse reactions and even death could occur
- Dogs, cats or attenders with a known hypersensitivity to insecticides or alcohol should avoid contact with FIPROFORT® PLUS Spot-on solution
- The product should not be used on puppies less than 8 weeks old and/or weighing less than 2kg and kittens less than 8 weeks old
- Do not use on sick (systemic diseases, fever) or convalescent dogs and cats.
- FIPROFORT® PLUS for dogs should not be used in cats as this could to overdosing.
- It is important to apply the dose to an area where the animal cannot lick it off, and to make sure that dogs do not lick each other following treatment. If licking occurs, a brief period of hypersalivation may occur, mainly due to the nature of the carrier.
- Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (skin discolouration, local alopecia, pruritis, erythema) and general pruritis or alopecia have been reported after use.
- Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs) or vomiting or respiratory signs have been observed after use.
- Animal should not be allowed to swim in water courses for 2 days after application.

Other warnings:

- The product can cause mucous membrane and eye irritation, so avoid contact with the mouth and eyes.
- 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 plain water.
- Avoid contact with the dog's eyes.
- Wash hands after use.

- Do not smoke, eat or drink during application.
- Treated animal should not be handled until the application site is dry and children should not be allowed to play with treated dogs until the application site is dry. It is therefore recommended that dogs are not treated during the day, but should be treated during the early evening, and that recently treated dogs should not be allowed to sleep with owners, especially children.
- Ensure that treated dogs and cats do not groom each other after treatment until dry.

Precautions:

Bathing/immersion in water within 2 days after application of the product and more frequent baths than once a week should be avoided. The emollient shampoos can be used before treatment, but decrease the duration of protection against fleas approximately 5 weeks when used weekly after application of the product.

Weekly shampooing with 2% chlorhexidine did not decrease the effectiveness of the product against fleas in a study of 6 weeks.

Pregnancy and Lactation: The safety of the product was demonstrated in breeding, pregnant and lactating bitches treated with multiple consecutive doses with up to 3 times the maximum recommended dose. FIPROFORT® PLUS for dogs can be used in breeding, pregnant and lactating bitches. FIPROFORT® PLUS for cats & kittens is safe for use in cats and kittens over 8 weeks of age and in breeding, pregnant or lactating queens.

Overdosage: The risk of experiencing adverse effects may however increase in cases of overdose, so dogs should always be treated with the correct pipette size according to bodyweight.

Further Information:

FIPROFORT® PLUS Spot-on for Dog is effective against flea infestation for approximately 35 days and against tick infestation for up to 28 days, depending on the level of environmental challenge. Newly arriving fleas are killed within 24 hours of landing on the animal. Re-treatment may safely be carried out at one month intervals.

FIPROFORT® PLUS Spot-on for cats and dogs is licensed for use as part of a strategy for the treatment of Flea Allergy Dermatitis. For this condition, monthly application to the allergic patient and to other dogs in the household is recommended.

FIPROFORT® PLUS Spot-on for Dog does not prevent all ticks attaching to the dog, but ticks will be killed in the first 24-48 hours after attachment, prior to full engorgement and therefore minimizing the risk of transmission of disease. Once dead, ticks will often drop off, but any remaining ticks may easily be removed by a gentle pull, preferably using tweezers. There may be an attachment of single ticks. For this reason transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

Fleas from pets often infest the dogs 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.

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

After the topical application of FIPROFORT® PLUS Spot-on for Dog, the product will spread from the site of treatment to cover the entire surface of the dog within 24 hours. After application, absorption of fipronil through the skin is slight.

Bathing or shampooing the dog up to one hour prior to treatment does not affect the efficacy of the product.

Storage: Store below 30°C.

Physical or Chemical Hazards: FLAMMABLE
Keep away from heat and open flame.

Container disposal: Fipronil and (S)-methoprene may adversely affect aquatic organisms. Do not discard the product or empty pipettes in ponds, rivers and streams. Securely wrap pipette in several layers of newspaper and discard in trash.

Presentation:

FIPROFORTSpot-on for Dogs upto 10 kg: Pipette of 0.67 ml

FIPROFORTSpot-on for Dogs over 10 kg upto 20 kg: Pipette of 1.34 ml

FIPROFOR Spot-on for Dogs over 20 kg upto 40 kg: Pipette of 2.68 ml

FIPROFORTSpot-on for Dogs over 40 kg upto 60 kg: Pipette of 4.02 ml

FIPROFOR PLUS Spot-on solution for Cats and Kittens 8 weeks or older: Pipette of 0.5 ml

For external application only.

For the treatment of cats and dogs only.



SAVA HEALTHCARE LIMITED

Plot No. 507-B to 512 GIDC Estate,
Wadhwan City – 363035, Surendranagar,
Gujarat, India

www.savavet.com