

Effipro Spot-On Solution for Dogs

Presentation

Spot-on solution containing 100mg/mL fipronil presented in plastic pipettes, each containing 0.67mL (67mg fipronil), 1.34mL (134mg fipronil), 2.68mL (268mg fipronil), 4.02ml (402mg fipronil).

Uses

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations. Insecticidal efficacy against new infestations with adult fleas persists for 8 weeks. The product has a persistent acaricidal efficacy for up to 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus*, *Dermacentor reticulatus*). If ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

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 veterinary surgeon.

Dosage and administration

Administer by topical application to the skin.

1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight

1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight

1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight

1 pipette of 4.02 ml per dog weighing over 40 kg and up to 60 kg bodyweight

For dogs over 60 kg use two pipettes of 2.68 ml.

Method of administration: Hold the pipette upright. Tap the narrow part of the pipette to ensure that the contents are within the main body of the pipette. Break the snap-off top of the spot-on pipette along the scored line.

Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the pet's back.

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.

Care should be taken to avoid excessive wetting of the hair with the product since this will cause a sticky appearance of hairs at the treatment spot. However, should this occur, it will disappear within 24 hours post application.

White deposits may also be seen at the site for up to 48 hours after application.

Treatment schedule: For optimal control of flea and/or tick infestation the treatment schedule can be based on the local epidemiological situation.

In the absence of safety studies, the minimum treatment interval is 4 weeks.

Contra-indications, warnings, etc

For animal treatment only. For external use only.

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

Do not use on sick (systemic diseases, fever...) or convalescent animals.

Do not use in rabbits, as adverse drug reactions and even death could occur.

Do not use in cases of hypersensitivity to the active substance or to any of excipients. Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

Do not apply the product on wounds or damaged skin.

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier. Among the extremely rare suspected adverse reactions, transient cutaneous reactions at the application site (squamosis, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms) or vomiting have been observed after use.

Operator warnings:

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water. If eye irritation persists seek medical advice and show the package leaflet or the label to the physician. Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use. Do not smoke, drink or eat during application.

Animals or operators with a known hypersensitivity to fipronil or excipients should avoid contact with the veterinary medicinal product.

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 should not be allowed to sleep with owners, especially children.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

Pharmaceutical precautions

Store below 30°C. Store in a dry place. Store in the original package. Keep out of reach of children. Flammable.

Further information

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. It acts by inhibiting the GABA complex, binding to the chloride channel and 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 acarids.

Fipronil exhibits an insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp) and ticks (*Rhipicephalus* spp, *Dermacentor* spp, *Ixodes* spp. including *Ixodes ricinus*) in the dog. Fleas will be killed within 24 h. Ticks will usually be killed within 48 h after contact with fipronil, however if ticks of some species (*Rhipicephalus sanguineus* and *Ixodes ricinus*) are present when the product is applied, all the ticks may not be killed within the first 48 hours.

Fipronil is mainly metabolised to its sulfone derivative (RM1602), which also possesses insecticidal and acaricidal properties. The concentrations of fipronil on the hair decrease with time.

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.

The product does not prevent ticks from attaching to the animals. If the animal has been treated prior to exposure to the ticks, the ticks will be killed in the first 24-48 hours after attachment. This will usually be prior to engorgement, minimising but not excluding the risk of transmission of diseases. Once dead, ticks will often drop off the animal, but any remaining ticks may be removed with a gentle pull.

Shampooing an hour prior to treatment does not affect the efficacy of the product against fleas.

Bathing/immersion in water within two days after application of the product should be avoided. Weekly immersion in water for one minute reduces the period of persistent insecticidal efficacy against fleas by one week.

For optimum control of flea problems in a multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Laboratory studies using fipronil have not shown any evidence of teratogenic or embryotoxic effect. Studies have not been carried out with this product in pregnant and lactating bitches. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

No adverse effects were observed in target animal safety studies in 2 month-old puppies, growing dogs and dogs weighing about 2 kg treated with the therapeutic dose on five consecutive days.

The risk of adverse effects may increase in cases of overdose. No known incompatibilities exist for the use of concurrently administered medicinal products.

The alcohol carrier may have adverse effects on painted, varnished or other household surfaces or furnishings.

Legal category

NFA-VPS

Packaging Quantities

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes. Not all pack sizes may be marketed.

Marketing authorisation number

Small dog: VM 05653/4151

Medium dog: VM 05653/4152

Large dog: VM 05653/4153

Very large dog: VM 05653/4154