SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Effipro 134 mg spot-on solution for medium dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 1.34 ml pipette contains:

Active substance:

Fipronil 134 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butyhydroxyanisole (E320)	0.268 mg
Butylhydroxytoluene (E321)	0.134 mg
Benzyl alcohol	
Diethylene glycol monoethyl ether	

Clear, colourless to yellow spot-on solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of flea (*Ctenocephalides* spp.) and tick (*Dermacentor reticulatus*) infestations.

Insecticidal efficacy against new infestations with adult fleas persists for up to 8 weeks.
The veterinary medicinal 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 veterinary medicinal product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

3.3 Contraindications

Do not use on puppies less than 2 months old and /or weighing less than 2kg in the absence of available data.
Do not use on sick (e.g. systemic diseases, fever…) or convalescent animals.
Do not use in rabbits, due a risk of adverse drug reactions or even death.
This veterinary medicinal product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Shampooing an hour prior to treatment does not affect the efficacy of the veterinary medicinal product against fleas.
Bathing/immersion in water within two days after application of the veterinary medicinal product should be avoided. Weekly immersion in water for one minute reduces the period of persistent insecticidal efficacy against fleas by one week.

The veterinary medicinal 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.

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.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Animals should be weighed accurately prior to treatment.

Avoid contact with the animal’s eyes. In the case of accidental eye contact, immediately rinse the eyes with clean water.

It is important to make sure that the veterinary medicinal 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

Do not apply the veterinary medicinal product on wounds or damaged skin.

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

Keep pipettes in original packaging until ready to use

People with a known hypersensitivity to fipronil or excipients (see section 2.) should avoid contact with the veterinary medicinal product.

This veterinary medicinal product can cause mucous membrane and eye irritation. Therefore, contact between the veterinary medicinal product and the mouth or eyes should be avoided.
In the case of accidental eye contact, immediately rinse the eyes with clean 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 skin. If this occurs, wash hands with soap and water.
Ingestion of the product is harmful. Prevent children getting access to the pipettes and discard the used pipettes immediately after applying the product.
In case of accidental ingestion of product seek medical advice immediately.

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.

Do not smoke, drink or eat during application. Wash hands after use.

Special precautions for the protection of the environment:

Fipronil may adversely affect aquatic organisms. Dogs should not be allowed to swim in water courses for 2 days after application.

Other precautions:

The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings.

3.6 Adverse events

Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction[1] (e.g. skin hair coat discoloration, alopecia, pruritus, erythema) Generalised itching, Alopecia general Hypersalivation[2] Neurological disorder[3] (e.g. Hyperesthesia, central nervous system depression and neurological symptoms) Vomiting Respiratory tract disorders

[1]Transient cutaneous reactions on the application site.
[2]If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.
[3]Reversible symptoms.

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 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:

Laboratory studies in dogs have not produced any evidence of teratogenic or embryotoxic effects.

Studies have not been carried out with this product in pregnant and lactating bitches. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

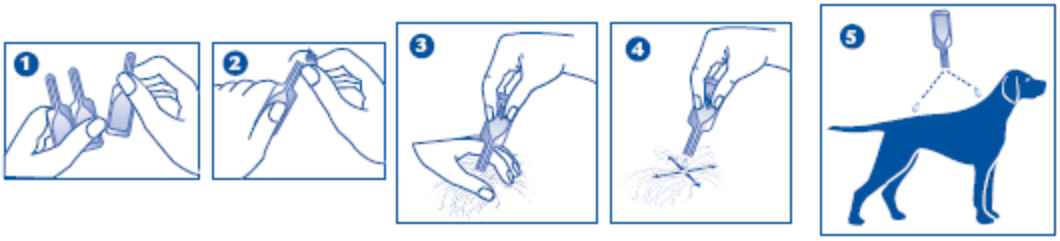
3.9 Administration routes and dosage

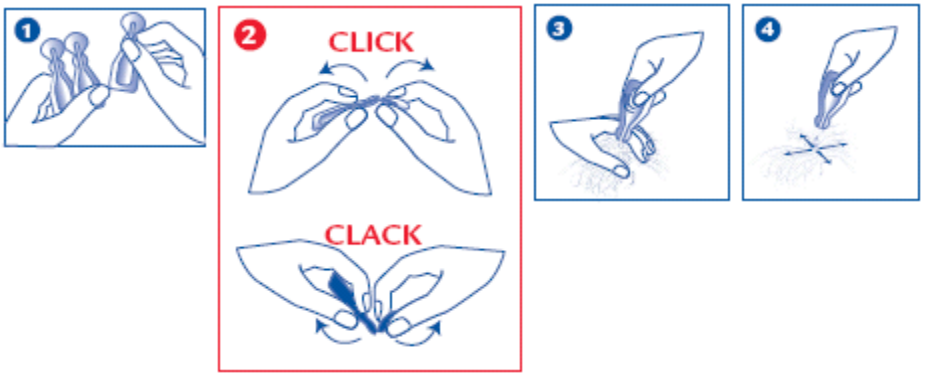
Route of administration and dosage:
External use only.
Administer by topical application to the skin according to the bodyweight as follows:
1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight.

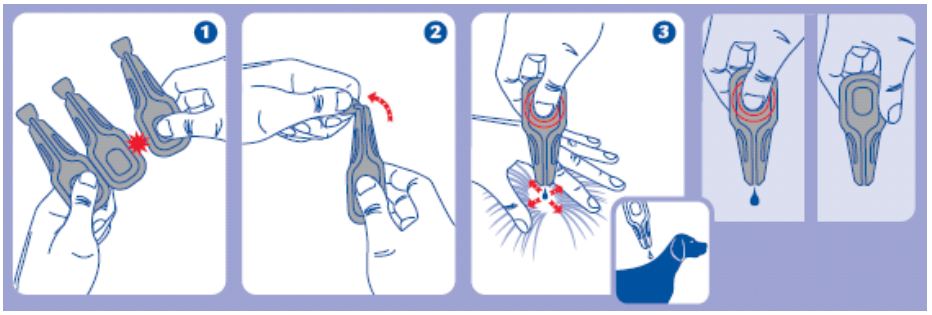
Method of administration:

Thermoformed pipettes:
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.

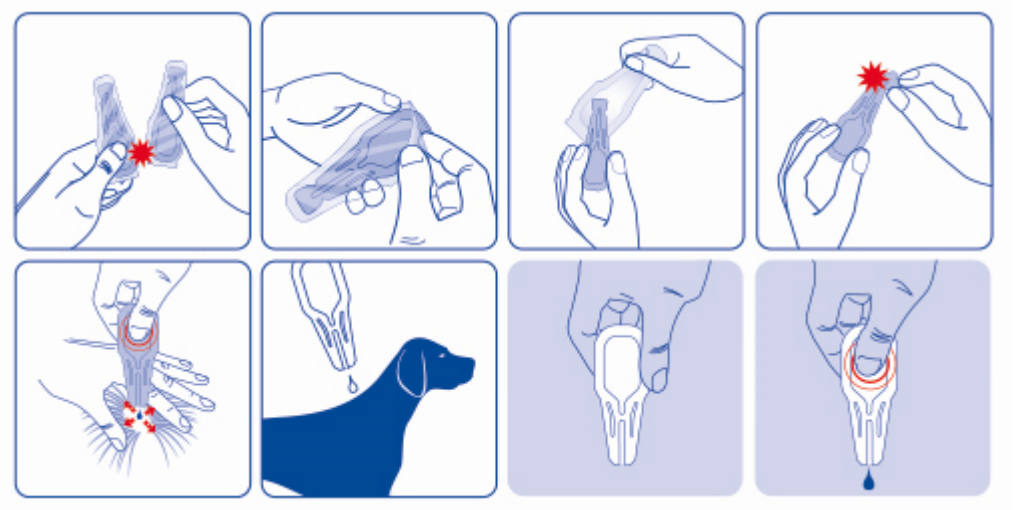
Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the pet's back.







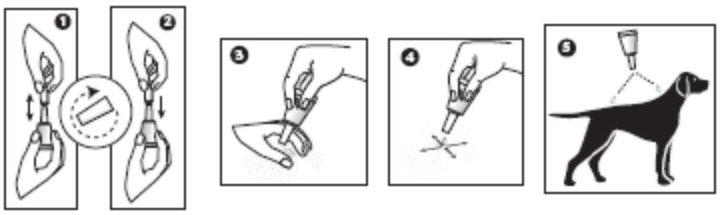
(Note: the shape of the marketed pipettes can be different as well as the pictures on the marketed boxes/package leaflets.)



(Note : The pipettes can be marketed in a blister. In this case, the above images will appear on the box and leaflet)

Polypropylene pipettes:
Remove the pipette from the blister packaging. Hold the pipette in an upright position, twist and pull the cap off. Turn the cap around and place the other end of the cap back on the pipette. Twist the cap to break the seal, then remove the cap from the pipette.

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 points along the pet's back.



It is important to make sure that the veterinary medicinal 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 veterinary medicinal 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.

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.

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

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 (see section 3.6) may increase in cases of overdose.

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: QP53AX15

4.2 Pharmacodynamics

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 already present when the veterinary medicinal product is applied, all of the ticks may not be killed within the first 48 hours.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale:
Thermoformed pipette: 3 years
Polypropylene pipette: 2 years

5.3 Special precautions for storage

Store below 30°C.
Store in a dry place.
Store in the original package.

5.4 Nature and composition of immediate packaging

Thermoformed pipettes: White or transparent multi-layer plastic single-dose pipettes containing an extractible volume of 1.34 ml.
The internal layers in contact with the veterinary medicinal product are made of polyacrylonitrile-methacrylate or polyethylene-ethylene vinyl alcohol-polyethylene. The white or transparent external complex is composed of polypropylene/ cyclic olefine copolymer/ polypropylene.
Boxes of 1, 2, 3, 4 or 6 pipettes.

Polypropylene pipettes: White polypropylene single-dose pipettes with an integral polyacetal cap for piercing the pipette, containing an extractible volume of 1.34 ml packaged in uncoloured plastic blister composed of polypropylene/cyclic olefine copolymer / polypropylene closed by heat sealing with a thermosealable lacquered aluminium foil and placed in a carton box or blister card.
Blister cards or boxes of 1, 2, 3, 4 or 6 pipettes.

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.

The veterinary medicinal product should not enter water courses as Fipronil may be dangerous for fish and other aquatic organisms.

Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty container.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBERS

Vm 05653/5085
Vm 05653/3053

8. DATE OF FIRST AUTHORISATION

10 June 2013

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

August 2025

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: 01 August 2025