SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fipralone duo 402 mg/120 mg spot-on solution for very large dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 4.02 ml pipette contains:

Active substances:

Fipronil	402.0 mg
Pyriproxyfen	120.6 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	0.804 mg
Butylhydroxytoluene E321	0.402 mg
Diethylene glycol monoethyl ether	

Clear, colourless to yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (40-60 kg).

3.2 Indications for use for each target species

To be used against infestations with fleas alone or in association with ticks.

Against fleas:
Treatment and prevention of infestations by fleas *(Ctenocephalides felis).* One treatment prevents further infestations for 7 weeks.
Prevention of the multiplication of fleas by preventing flea eggs developing into adult fleas for 12 weeks after application.

Against ticks:
Treatment of infestations by ticks (*Ixodes ricinus).*
One treatment provides persistent acaricidal efficacy for 2 weeks against *Ixodes ricinus*, and for 4 weeks against *Dermacentor reticulatus* and *Rhipicephalus sanguineus*.
If ticks of some species (*Dermacentor reticulatus*, *Rhipicephalus sanguineus*) are present at the time of application, not all ticks may be killed within 48 hours.

3.3 Contraindications

Do not use in rabbits, as adverse reactions and even death could occur.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

3.4 Special warnings

Shampooing or immersion of the animal in water directly after treatment may reduce the duration of activity. The veterinary medicinal product remains effective against fleas for 5 weeks when the dog is shampooed at monthly intervals after treatment. If the dog requires shampooing, it is better to do so before treatment.
Water immersion repeated on two occasions post treatment did not affect adulticidal efficacy against fleas nor the efficacy related to the prevention of the development of flea eggs into adult fleas.

The influence of water immersion or shampooing of the dog on the efficacy of the veterinary medicinal product against ticks has not been evaluated.

At the beginning of the control measures, in the case of an infestation, the animal's basket, bedding and regular resting areas such as carpets and soft furnishings should be treated, with a suitable insecticide and vacuumed regularly.

To reduce environmental flea challenge, all animals living in the same household should also be treated with a suitable flea control product.

The veterinary medicinal product does not prevent ticks from attaching to animals. Transmission of infectious disease by ticks cannot be completely excluded if conditions are unfavourable.
Immediate efficacy has been demonstrated against *Ixodes ricinus*, indicating that ticks of this species are likely to be killed within 48 hours of product application. If *Dermacentor reticulatus* or *Rhipicephalus sanguineus* ticks are present when the veterinary medicinal product is applied, these ticks may not be killed within the first 48 hours.
Once dead, ticks will often drop off the animal. Any remaining ticks should be carefully removed, ensuring that their mouth parts are not left within the skin.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For external use only.
Animals should be weighed accurately prior to treatment.
In absence of safety data, the veterinary medicinal product should not be used in puppies less than 10 weeks old and/or weighing less than 2 kg.
Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the recipient dogs. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.
Do not apply the veterinary medicinal product on wounds or damaged skin.
In the absence of additional safety studies, do not repeat the treatment at intervals of less than 4 weeks.

The use of the veterinary medicinal product has not been studied in sick and debilitated dogs.

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

The veterinary medicinal product may cause neurotoxicity.
The veterinary medicinal product may be harmful if swallowed.
Avoid ingestion including hand to mouth contact.
Do not smoke, drink or eat during application.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal product can cause eye and mucous membrane irritation.
Avoid contact with skin, eye and mouth, including hand to eye contact.
In case of accidental skin or eye contact, immediately and thoroughly flush with water. If skin or eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
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 should not be allowed to sleep with owners, especially children.
Keep the pipettes in the original packaging until ready for use and dispose of used pipettes immediately.

Special precautions for the protection of the environment:

Fipronil and pyriproxyfen may adversely affect aquatic organisms. Dogs should be prevented from accessing streams and rivers for 48-hours following treatment (see also section 5.5).

Other precautions:

The veterinary medicinal product may have adverse effects on painted, varnished or other household surfaces or furnishings. Allow the application site to dry before permitting contact with such materials.

3.6 Adverse events

Dogs (40-60 kg):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction[1] (e.g. Application site skin squamosis, Application site alopecia, Application site pruritus, Application site erythema, Application site skin discolouration) Generalised itching, Alopecia Hypersalivation, Vomiting Neurological disorder[2] (e.g. Hyperaesthesia, Central nervous system depression, Neurological symptoms) Respiratory signs

Undetermined frequency (Cannot be estimated from the available data)	Application site greasy fur[1,3], Application site skin scaling[1,3,4]

[1]Transient
[2]Reversible
[3]Cosmetic effect
[4]Slight

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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:

Laboratory studies using fipronil and pyriproxyfen have not produced any evidence of teratogenic or embryotoxic effects. 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

Spot-on use.

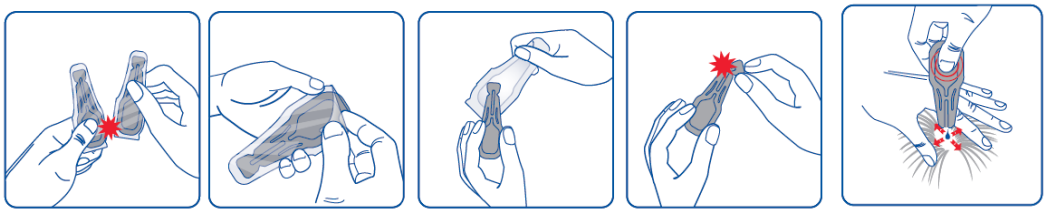
Dosage:
Apply one pipette of 4.02 ml per dog for a dog weighing from 40 to 60 kg corresponding to the minimal recommended dose of 6.7 mg fipronil /kg b.w. and 2 mg pyriproxyfen/kg b.w.

Volume	Dog weight	Fipronil (mg)	Pyriproxyfen (mg)
0.67 ml	2-10 kg	67	20.1
1.34 ml	10-20 kg	134	40.2
2.68 ml	20-40 kg	268	80.4
4.02 ml	40-60 kg	402	120.6

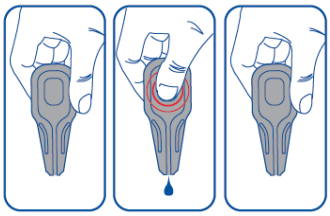
For dogs over 60 kg the appropriate combination of pipettes should be used.

Method of administration:
Remove the pipette from the overblister. 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 on base of the neck before the shoulder blades until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently several times to

empty the contents. If necessary the contents of the pipette can be administered at one or two additional point(s) along the pet's back to avoid run-off or more superficial application to the hair coat, particularly in large dogs.



Drop stop system (the product is released only by pressing the body of the pipette).



One pipette provides a single treatment, with the possibility to repeat administrations on a monthly basis.
For optimal control of flea and tick infestations and flea multiplication, the treatment schedule can be based on the local epidemiological situation.

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

No serious adverse effects were observed in a safety study in 10-week old puppies treated with up to 5 times the maximum recommended dose 3 times at intervals of 4 weeks and with the maximum recommended dose 6 times at intervals of 4 weeks.
The risk of experiencing adverse reactions (see section 3.6) may however increase with overdosing, so animals should always be treated with 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 INFORMATION

4.1 ATCvet code: QP53AX65

4.2 Pharmacodynamics

Fipronil is an insecticide and acaricide belonging to the phenylpyrazole family. Fipronil and its metabolite fipronil sulfone act at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA) as well as desensitising

(D) and non-desensitising (N) channels gated by glutamate (Glu, unique invertebrate ligand-gated chloride channels), 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 acarid.

Pyriproxyfen is an insect growth regulator (IGR) of the class of compounds known as juvenile hormone analogues. Pyriproxyfen sterilises adult fleas and inhibits the development of immature stages. The molecule prevents, by contact, the emergence of adult insects by blocking the development of eggs (ovicidal effect), larvae and pupae (larvicidal effect), which are subsequently eliminated. Following contact and/or ingestion by adult fleas, the molecule also acts by sterilising eggs during their maturation and before being laid. The molecule prevents contamination of the environment of treated animals with the immature stages of fleas

Combination of fipronil and pyriproxyfen provides an insecticidal and acaricidal activity against fleas (*Ctenocephalides felis*), ticks (*Rhipicephalus sanguineus*, *Dermacentor reticulatus*, *Ixodes ricinus*) in addition to preventing flea eggs developing into adult fleas.

4.3 Pharmacokinetics

Following topical application of the veterinary medicinal product to dogs, under the normal conditions of use, fipronil and pyriproxyfen are well distributed across the haircoat of the dog by 24 hours.
The major metabolite of Fipronil is the sulfone derivative, which also possesses insecticidal and acaricidal properties.
The concentrations of fipronil, fipronil sulfone and pyriproxyfen in the haircoat decrease over time but are still detectable for at least 84 days after application.
After administration of the veterinary medicinal product, the plasmatic peak concentration is reached between 3 to 7 days for fipronil and between 7 to 14 days for fipronil sulfone. The plasmatic peak concentration of pyriproxyfen is reached between 1 to 3 days after administration.
The plasmatic concentrations of fipronil and pyriproxyfen decrease over time and the concentrations are quantifiable up to 50 days after application.

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

Do not store above 30 °C.
Store in a dry place.
Keep the blister pack in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Transparent multi-layer plastic single-dose pipettes containing 4.02 ml obtained by thermoforming a transparent bottom complex (polyacrylonitrile-methacrylate or polyethylene-ethylene vinyl alcohol-polyethylene), polypropylene, cyclic olefin copolymer, polypropylene) and closed by heat sealing with a lid complex (polyacrylonitrile-methacrylate or polyethylene-ethylene vinyl alcohol-polyethylene), aluminium, polyethylene-terephthalate).

The boxes contain individual pipette(s) placed in overblister(s) made from polypropylene, cyclic olefin copolymer, polypropylene and closed with lid made from polyethylene-terephthalate, aluminium, polypropylene.

Boxes of 1, 2, 3, 4 and 6 pipettes.

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.

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

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

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 THE MARKETING AUTHORISATION HOLDER

Alfamed

7. MARKETING AUTHORISATION NUMBER

Vm 17902/3009

8. DATE OF FIRST AUTHORISATION

15 July 2015

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

May 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Gavin Hall
Approved: 24 July 2025