1 NAME OF THE VETERINARY MEDICINAL PRODUCT

EFFIPRO 2.5 mg/ml cutaneous spray, solution for cats and dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains

Active substance:
Fipronil 2.5 mg

Excipient:
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, solution.Clear, colourless to yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.
Treatment of tick infestation (*Ixodesricinus, Rhipicephalussanguineus*) in dogs and cats.
Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).
The product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

Insecticidal efficacy against new infestations with adult fleas persists for up to 6 weeks in cats and up to 3 months in dogs, depending on environmental challenge.
The product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

4.3 Contraindications

Do not use on sick (systemic diseases, fever…) or convalescent animals.
Do not use in rabbits, as adverse reactions and even death could occur.
Do not use in cases of hypersensitivity to the active substance or to any of excipients.

4.4 Special warnings for each target species

When used as part of a strategy for the treatment of flea allergy dermatitis, monthly applications to the allergic patient and to other cats and dogs in the household are recommended.

For optimum efficacy, it is not recommended to bathe or shampoo animals in the two days prior to or following treatment with the product. Bathing or shampooing up to four times in two months has been shown to have no significant effect on the residual efficacy of the product. Monthly treatment is recommended when more frequent shampooing is carried out.

Treatment of bedding, carpets and soft furnishings with a suitable insecticide will aid reduction in environmental challenge and maximise the duration of protection against re-infestation provided by the product.

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.

There may be an attachment of single ticks. For this reason transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.
The product is not suitable for direct treatment of the environment.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dosage.
Avoid contact with the animal's eyes.
Do not spray directly onto areas of broken skin.
Allow treated animals to dry in a well ventilated room.
Do not confine animals in an enclosed space or pet carrier until the coat is totally dry.

It is important to make sure that animals do not lick each other following treatment.

Keep treated animals away from fires or other sources of heat, and surfaces likely to be affected by the alcohol spray, for at least 30 minutes following spraying and until the fur is totally dry.

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

This product can cause mucous membrane and eye irritation. Therefore, contact between the product and the mouth or eyes should be avoided.

People with known hypersensitivity to fipronil or excipients 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 plain water.

Treated animals should not be handled until the fur is dry, and children should not be allowed to play with treated animals until the fur 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.

Spray animals in the open air or a well ventilated room.
Do not breathe spray. Do not smoke, drink or eat during application.
Wear PVC or nitrile gloves during treatment of animals. It is recommended to wear a waterproof apron for the protection of clothing. If clothing becomes heavily wetted with the product, it should be removed and washed before re-use.
Dispose of gloves after use and then wash hands with soap and water.

Wash splashes from skin with soap and water immediately. If irritation occurs, seek medical advice. People with known sensitivity or asthma may be particularly sensitive to the product. Do not use product if you have previously experienced a reaction to it.

Treatment of multiple animals: Good ventilation is particularly important where several animals are to be treated. Treat multiple animals outside, or reduce the build up of vapour by removing the animals from the treatment room while the alcohol is evaporating and ensure that the treatment room is well ventilated between individual treatments. In addition, ensure that the drying room is well ventilated and avoid housing several recently treated animals within the same air space.

Other precautions

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

4.6 Adverse reactions (frequency and seriousness)

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 erythema such as pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurological signs (hyperaesthesia, depression, nervous signs), vomiting or respiratory signs have been observed after use.

4.7 Use during pregnancy, lactation or lay

Laboratory studies did not reveal any teratogenic effect of fipronil in the rat and rabbit. Fipronil is very well tolerated by puppies following treatment of the lactating bitch. Data is not available from specific studies during pregnancy in bitches, pregnancy in queens or in nursing queens. The safety of the veterinary medicinal product has not been established, therefore, use only in accordance with the risk/benefit assessment by the veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

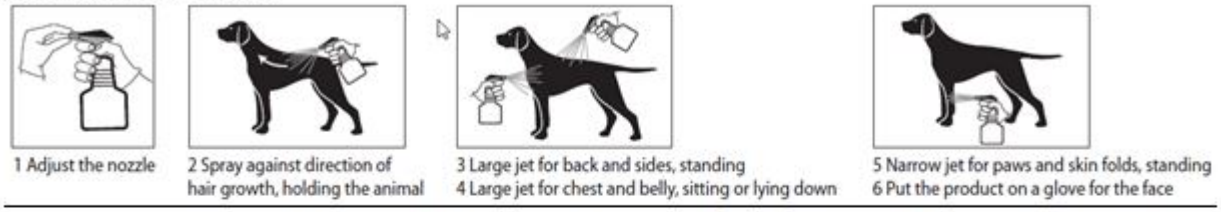
Route of administration:
Mechanical pump spray for external use only.
The pump delivers 0.5 ml (100 ml bottle) or 1.5 ml (250 ml bottle) or 3ml (500 ml bottle) spray per pump.

Dosage:
In order to dampen the coat down to the skin, apply 3 to 6 ml per kg bodyweight, (7.5 to 15 mg of active ingredient per kg bodyweight), depending on the length of hair.
This dosage can be achieved with 6 to 12 pump applications per kg bodyweight of the 100 ml presentation, or 2 to 4 pump applications of the 250 ml presentation or 1 to 2 pump application(s) of the 500 ml presentation.

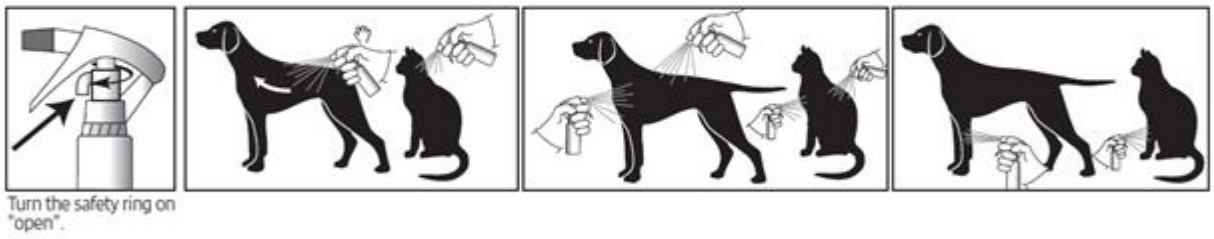
Depending on the coat length,
the 100 ml presentation allows 4 to 8 treatments of a 4 kg cat or up to 3 treatments of a 10 kg dog,
the 250 ml presentation allows 2 to 4 treatments of a 20 kg dog,
the 500 ml presentation allows 2 to 4 treatments of a 40 kg dog.

Method of administration:
For the 250 and 500 ml bottles, adjust the pump nozzle to spray setting.
Spray the entire body of the animal, and apply from a distance of approximately 10-20 cm. Apply against the lay of the hair and make sure that the entire coat of the animal is dampened. Ruffle the coat, especially in long haired animals, so that the product penetrates down to the skin. For treatment of the head region, and when treating young or nervous pets, application may be carried out by spraying onto a gloved hand and rubbing the product into the coat. Allow to dry naturally. Do not towel dry.

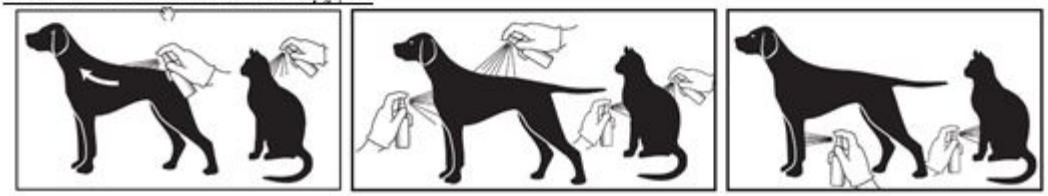
250 and 500 ml bottles:



100 ml bottle with a trigger:



100 ml bottle without a trigger:



(NOTE: Either the first series of pictograms or the second one will appear on the 100 ml bottle but not both.)

Properties:
The formulation contains a coating agent. Therefore, spraying builds up a film and makes the fur glossy.

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.
Puppies and kittens from 2 days of age may be safely treated.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The risk of adverse effects may increase in cases of overdose.Start an appropriate symptomatic treatment in case of overdosing.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use.
ATCvet code: QP53AX15

5.1 Pharmacodynamic properties

Fipronil is an insecticide and acaricide from 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 the membrane. This results in uncontrolled activity of the central nervous system and death in insects and acarids.

Fipronil exhibits insecticidal and acaricidal activity against fleas (*Ctenocephalides* spp), ticks (*Rhipicephalus* spp. *Ixodes* spp) and lice (*Trichodectes* spp. and *Felicola* spp). in the dog and cat.

5.2 Pharmacokinetic particulars

Absorption
The amount of fipronil absorbed by the skin in the dog, after application of the spray to the coat and skin is extremely slight to negligible.

Distribution
The persistence of fipronil on the hair is very long (on average 52.5 ± 11.5 days), given that the limit of quantification of the assay method is 0.25 µg/g.

Biotransformation
In all species fipronil is mainly metabolised to its sulphone derivative (RM1602), which also possesses insecticidal and acaricidal properties.The RM1602 detected on the hair after spray application in dogs may be explained by its presence in the original raw material.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Copovidone
Isopropyl Alcohol
Water, Purified

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale : 3 years.
Shelf-life after first opening the immediate packaging : 1 year.

6.4 Special precautions for storage

Highly flammable.
Do not store above 25°C.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

100 ml filled in high density polyethylene white opaque bottle hermetically closed with a mechanical pump spray delivering 0.5 ml per spray (plunger in low density polyethylene).
250 ml filled in high density polyethylene white opaque bottle hermetically closed with a mechanical trigger pump delivering 1.5 ml per spray (plunger in low density polyethylene).
500 ml filled in high density polyethylene white opaque bottle hermetically closed with a mechanical trigger pump delivering 3 ml per spray (plunger in low density polyethylene).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
The product should not enter water courses as this may be dangerous for fish or other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

7 MARKETING AUTHORISATION HOLDER

Virbac
1ère avenue
2065 M LID
06516 Carros
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA10988/072/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15th May 2009
Date of last renewal: 15th May 2014

10 DATE OF REVISION OF THE TEXT

February 2018