

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 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 contains:

### Active substance:

Fipronil 2.5 mg

### Excipients:

Qualitative composition of excipients and other constituents
Copovidone
Isopropyl Alcohol
Water, Purified

Clear, colourless to yellow solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs and cats.

### 3.2 Indications for use for each target species

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.

Treatment of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*) in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

The veterinary medicinal 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 veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

### 3.3 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 the excipients.

### 3.4 Special warnings

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 veterinary medicinal 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 veterinary medicinal 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 veterinary product medicinal.

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 veterinary medicinal product is not suitable for direct treatment of the environment.

### **3.5 Special precautions for use**

#### Special precautions for safe use in the target species:

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 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.

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 veterinary medicinal 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 immediately and show the package leaflet or the label to the physician.

People with known sensitivity or asthma may be particularly sensitive to the veterinary medicinal product. Do not use veterinary medicinal 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.

#### Special precautions for the protection of the environment:

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

### **3.6 Adverse events**

Dogs and cats:

Very rare ( $< 1$ animal / 10,000 animals treated, including isolated reports):	Skin disorders (e.g. Erythema, Pruritus, Alopecia) <sup>1</sup>  Hypersalivation <sup>2</sup> , Vomiting  Neurological disorder (e.g. Hyperesthesia, Central nervous system depression, Neurological signs) <sup>3</sup>  Respiratory tract disorders
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<sup>1</sup>Transient cutaneous reactions.

<sup>2</sup>If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

<sup>3</sup>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 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**

#### Pregnancy and lactation:

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 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**

Cutaneous use.

Route of administration:

Mechanical pump spray for external use only.

The pump delivers 0.5 ml (100 ml bottle) or 1.3 ml (250 and 500 ml bottles) spray per pump.

Dosage:

100 ml bottle: 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.

250 and 500 ml bottles: In order to dampen the coat down to the skin, apply 3.9 to 5.2 ml per kg bodyweight, (9.8 to 13 mg of active ingredient per kg bodyweight), depending on the length of hair.

This dosage can be achieved with 3 to 4 pump applications per kg bodyweight of the 250 or 500 ml presentations.

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 3 treatments of a 20 kg dog,

the 500 ml presentation allows 2 to 3 treatments of a 40 kg dog.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Method of administration:

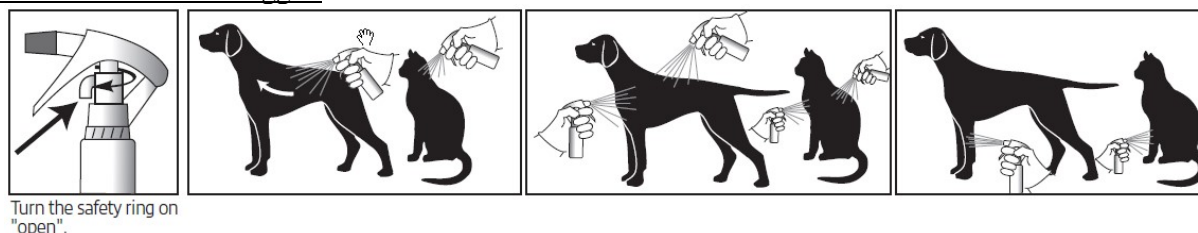
For the 250 and 500 ml bottles, adjust the pump nozzle to spray setting.

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 veterinary medicinal 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 veterinary medicinal product into the coat. Allow to dry naturally. Do not towel dry.

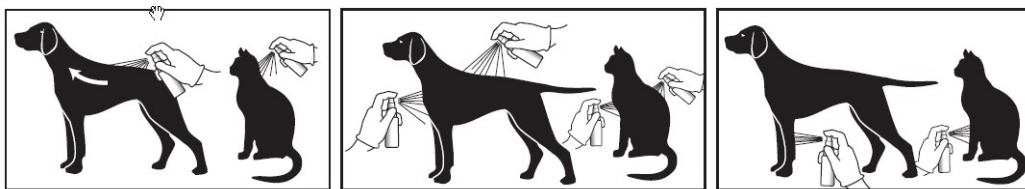
250 and 500 ml bottles:



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.

### **3.10 symptoms of overdose (and where applicable, emergency procedures and antidotes)**

The risk of adverse effects may increase in cases of overdose.

Start an appropriate symptomatic treatment in case of overdosing.

### **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 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.

### **4.3 Pharmacokinetics**

#### 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  $52.5 \pm 11.5$  days), given that the limit of quantification of the assay method is  $0.25 \mu\text{g/g}$ .

#### 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.

## **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.

Shelf life after first opening the immediate packaging: 1 year.

### **5.3 Special precautions for storage**

Highly flammable.

Do not store above  $25^{\circ}\text{C}$ .

Protect from direct sunlight.

### **5.4 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 and 500 ml filled in high density polyethylene white opaque bottle hermetically closed with a mechanical trigger pump delivering 1.3 ml per spray (plunger in low density polyethylene).

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 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**

VIRBAC

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

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

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription [BE, BG, CY, EL, HU, IE, SE, SI].

Veterinary medicinal product not subject to prescription [AT, CZ, DE, DK, EE, ES, FR, IT, LV, LT, LU, NL, PL, PT, RO, SK].

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



**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (same information as for an OUTER PACKAGE)**

**100 ml SPRAY**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Effipro 2.5 mg/ml cutaneous spray, solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Fipronil 2.5 mg/ml

**3. PACKAGE SIZE**

100 ml

**4. TARGET SPECIES**

Cats and dogs.

**5. INDICATIONS**

For products not subject to veterinary prescription.

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.

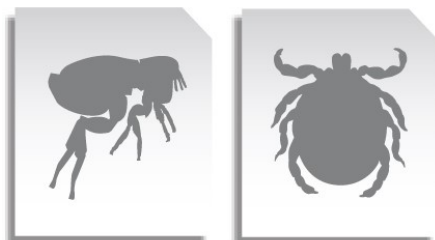
Treatment of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*) in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

The veterinary medicinal 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 3 months in dogs, depending on environmental challenge.

The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.



Fleas & Ticks

**6. ROUTES OF ADMINISTRATION**

Cutaneous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 1 year.

**9. SPECIAL STORAGE PRECAUTIONS**

Highly flammable.

Do not store above 25°C.

Protect from direct sunlight.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (same information as for an OUTER PACKAGE)**

**250 ml SPRAY**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Effipro 2.5 mg/ml cutaneous spray, solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Fipronil 2.5 mg/ml

**3. PACKAGE SIZE**

250 ml

**4. TARGET SPECIES**

Cats and dogs.

**5. INDICATIONS**

For products not subject to veterinary prescription.

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.

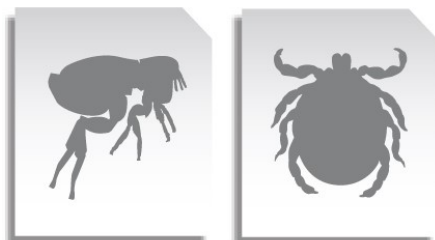
Treatment of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*) in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

The veterinary medicinal 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 3 months in dogs, depending on environmental challenge.

The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.



Fleas & Ticks

**6. ROUTES OF ADMINISTRATION**

Cutaneous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 1 year

**9. SPECIAL STORAGE CONDITIONS**

Highly flammable.

Do not store above 25°C.

Protect from direct sunlight.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the reach and sight of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (same information as for an OUTER PACKAGE)**

**500 ml SPRAY**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Effipro 2.5 mg/ml cutaneous spray, solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Fipronil 2.5 mg/ml

**3. PACKAGE SIZE**

500 ml

**4. TARGET SPECIES**

Cats and dogs.

**5. INDICATIONS**

For products not subject to veterinary prescription.

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.

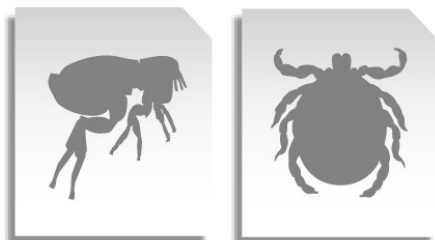
Treatment of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*) in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

The veterinary medicinal 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 3 months in dogs, depending on environmental challenge.

The veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.



Fleas & Ticks

**6. ROUTES OF ADMINISTRATION**

Cutaneous use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 1 year

**9. SPECIAL STORAGE CONDITIONS**

Highly flammable.

Do not store above 25°C.

Protect from direct sunlight.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

**11. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

VIRBAC

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}



## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

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

### 2. Composition

Each ml contains:

**Active substance:**

Fipronil 2.5 mg

Clear, colourless to yellow solution.

### 3. Target species

Dogs and cats.

### 4. Indications for use

Treatment of flea infestation (*Ctenocephalides* spp.) in dogs and cats.

Treatment of tick infestation (*Ixodes ricinus*, *Rhipicephalus sanguineus*) in dogs and cats.

Treatment of biting lice infestations in dogs (*Trichodectes canis*) and cats (*Felicola subrostratus*).

The veterinary medicinal 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 veterinary medicinal product has a persistent acaricidal efficacy for up to 4 weeks against ticks, depending on the level of environmental challenge.

### 5. 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 the excipients.

### 6. Special warnings

Special warnings:

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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product is not suitable for direct treatment of the environment.

#### Special precautions for safe use in the target species:

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 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.

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 veterinary medicinal 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 immediately and show the package leaflet or the label to the physician.

People with known sensitivity or asthma may be particularly sensitive to the veterinary medicinal product. Do not use veterinary medicinal 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.

#### Special precautions for the protection of the environment:

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

#### Pregnancy and lactation:

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 according to the benefit-risk assessment by the responsible veterinarian.

#### Overdose:

The risk of adverse effects may increase in cases of overdose.

Start an appropriate symptomatic treatment in case of overdosing.

### **7. Adverse events**

Dogs and cats:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):
Skin disorders (e.g. Erythema, Pruritus, Alopecia) <sup>1</sup>
Hypersalivation <sup>2</sup> , Vomiting
Neurological disorder (e.g. Hyperesthesia, Central nervous system depression, Neurological signs) <sup>3</sup>
Respiratory tract disorders

<sup>1</sup>Transient cutaneous reactions.

<sup>2</sup>If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

<sup>3</sup>Reversible symptoms.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

### **8. Dosage for each species, routes and method of administration**

Cutaneous use.

#### Route of administration:

Mechanical pump spray for external use only.

The pump delivers 0.5 ml (100 ml bottle) or 1.3 ml (250 and 500 ml bottles) spray per pump.

#### Dosage:

100 ml bottle: 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.

250 and 500 ml bottles: In order to dampen the coat down to the skin, apply 3.9 to 5.2 ml per kg bodyweight, (9.8 to 13 mg of active ingredient per kg bodyweight), depending on the length of hair. This dosage can be achieved with 3 to 4 pump applications per kg bodyweight of the 250 or 500 ml presentations.

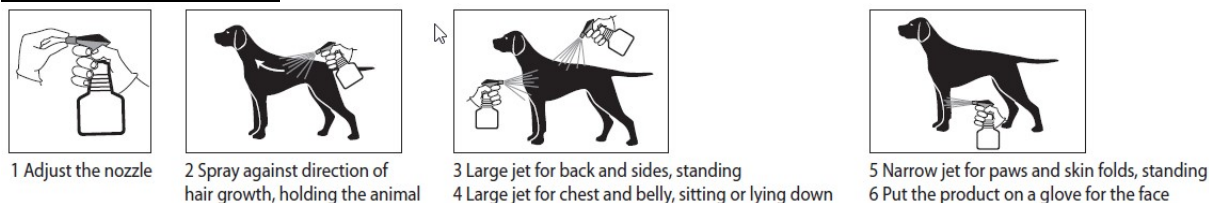
Depending on the coat length,  
the 100 ml presentation allows 4 to 8 treatments of a 4 kg cat or up to 3 treatments of a 10 kg dog,  
the 250 ml presentation allows 2 to 3 treatments of a 20 kg dog,  
the 500 ml presentation allows 2 to 3 treatments of a 40 kg dog.

Underdosing could result in ineffective use and may favour resistance development.  
To ensure a correct dosage, body weight should be determined as accurately as possible.

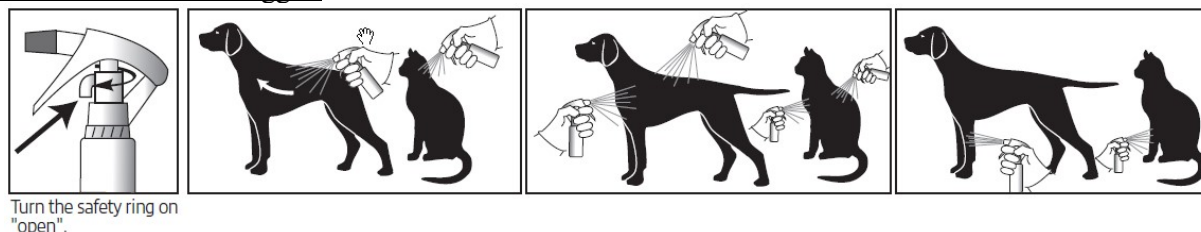
## 9. Advice on correct administration

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 veterinary medicinal 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 veterinary medicinal product into the coat. Allow to dry naturally. Do not towel dry.

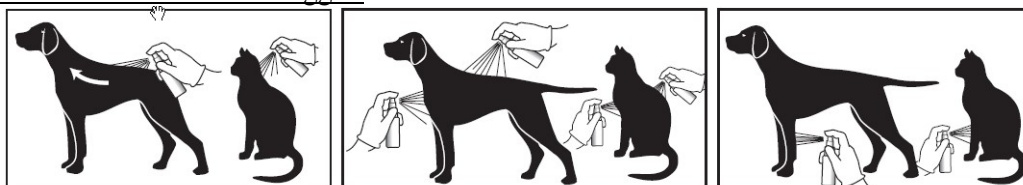
### 250 and 500 ml bottles:



### 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.

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

Highly flammable.

Do not store above 25°C.

Protect from direct sunlight.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 1 year.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater or household waste.

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.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

#### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription [BE, BG, CY, EL, HU, IE, SE, SI].

Veterinary medicinal product not subject to prescription [AT, CZ, DE, DK, EE, ES, FR, IT, LV, LT, LU, NL, PL, PT, RO, SK].

#### **14. Marketing authorisation numbers and pack sizes**

##### Pack sizes:

1 x 100 ml bottle

1 x 250 ml bottle

1 x 500 ml bottle

Not all pack sizes may be marketed.

**15. Date on which the package leaflet was last revised**

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

**16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

VIRBAC  
1<sup>ère</sup> avenue 2065m LID  
06516 Carros  
France

Local representative(s) and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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