

## **SUMMARY OF PRODUCT CHARACTERISTICS** **FOR CATS**

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

EFFIPRO 50 mg spot-on solution for cats

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One 0.5 ml pipette contains :

**Active substance:**

Fipronil 50 mg

**Excipients:**

Butylhydroxyanisole E320 0.1 mg/pipette

Butylhydroxytoluene E321 0.05 mg/pipette

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Spot-on solution.

Clear, colourless to yellow solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cats.

#### **4.2 Indications for use**

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

The product has a persistent acaricidal efficacy for up to 2 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.

#### **4.3 Contraindications**

In the absence of available data, the product should not be used on kittens less than 2 months old and/or weighing less than 1 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.

#### **4.4 Special warnings for each target species**

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.

No data on the effect of bathing/shampooing on the efficacy of the product in cats are available. However, based on information available for dogs, shampooing an hour prior to treatment does not affect the efficacy of the product against fleas.

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.

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

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.

##### **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.

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 (see section 6.1.) 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.

##### **Other precautions**

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

#### **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 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.

#### 4.7 Use during pregnancy and lactation

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

#### 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 and dosage:

External use only.

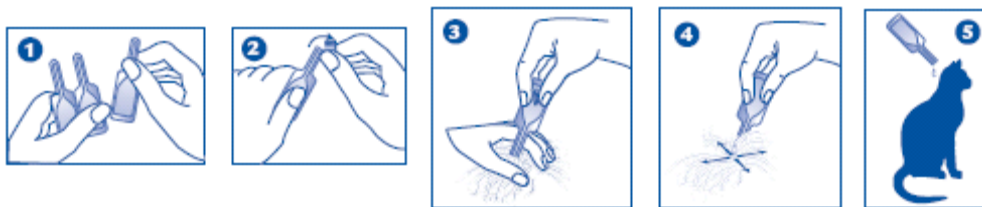
Administer by topical application to the skin 1 pipette of 0.5 ml per animal.

##### 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 cat's back, preferably at the base of the head and between the shoulders.

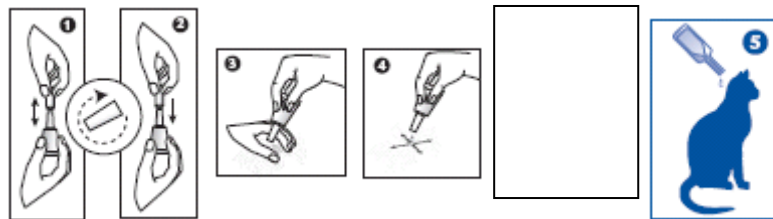


##### *Polypropylene pipettes:*

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 cat's back, preferably at the base of the head and between the shoulders.



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.

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

No adverse effects were observed in target animal safety studies in cats and kittens aged 2 months and older and weighing about 1 kg treated at five times the recommended dose (daily therapeutic dose applied on five consecutive days) for three consecutive months except for itching and vomiting that occurred once. The risk of adverse effects may increase in cases of over-dose.

#### **4.11 Withdrawal period**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

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

#### **5.1 Pharmacodynamic properties**

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 cat.

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.

## 5.2 Pharmacokinetic particulars

In vitro, fipronil is mainly metabolised with subcellular liver fractions to its sulfone derivative. However, this may be of limited relevance 'in vivo' as fipronil is poorly absorbed in the cat. The concentrations of fipronil on the hair decrease with time.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Butylhydroxyanisole E320  
Butylhydroxytoluene E321  
Benzyl alcohol  
Diethylene glycol monoethyl ether

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale : 18 months.

### 6.4. Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

*Thermoformed pipettes:* White multi-layer plastic single-dose pipette containing an extractible volume of 0.5 ml.

The internal layers in contact with the product are made of polyacrylonitrile-methacrylate. The white external complex is composed of polypropylene/ cyclic olefine copolymer/ polypropylene.

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

*Polypropylene pipettes:* White polypropylene single-dose pipette containing an extractible volume of 0.5 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, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal product 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. Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

**7. MARKETING AUTHORISATION HOLDER**

Virbac S.A.  
1<sup>ère</sup> avenue – 2065 m – L.I.D.  
06516 Carros  
FRANCE  
+ 33 (0)4 92 08 73 04  
+ 33 (0)4 92 08 73 48

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

Vm 05653/4150

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

26 November 2008

**10. DATE OF REVISION OF THE TEXT**

November 2008

## **SUMMARY OF PRODUCT CHARACTERISTICS** **FOR SMALL DOGS**

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

EFFIPRO 67 mg spot-on solution for small dogs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One 0.67 ml pipette contains :

**Active substance:**

Fipronil                    67 mg

**Excipients:**

Butylhydroxyanisole E320    0.134 mg/pipette

Butylhydroxytoluene E321    0.067 mg/pipette

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Spot-on solution.

Clear, colourless to yellow solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs.

#### **4.2 Indications for use**

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 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.

#### **4.3 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, as adverse reactions and even death could occur.



This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

Do not use in cases of hypersensitivity to the active substance or to any of excipients.

#### **4.4 Special warnings for each target species**

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.

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.

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.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.

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

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

Animals should be weighed accurately prior to treatment.

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

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

Do not apply the product on wounds or damaged skin.

##### **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.

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.

Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.

Animals or operators with a known hypersensitivity to fipronil or excipients (see section 6.1.) 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.

### **Other precautions**

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

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

### **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 on the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.

### **4.7 Use during pregnancy and lactation**

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.

### **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 and dosage:

External use only.

Administer by topical application to the skin according to the bodyweight as follows :

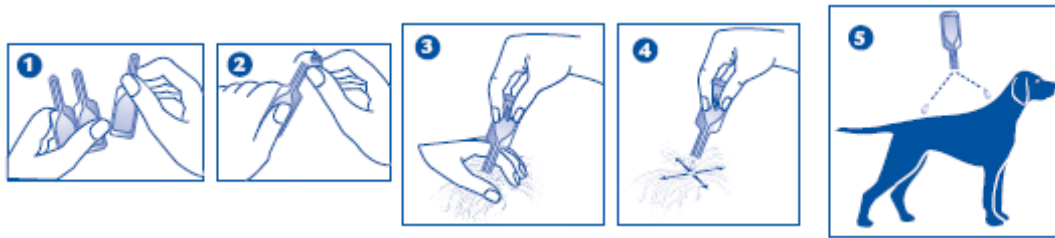
1 pipette of 0.67 ml per dog weighing over 2 kg and up to 10 kg bodyweight.

#### 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.

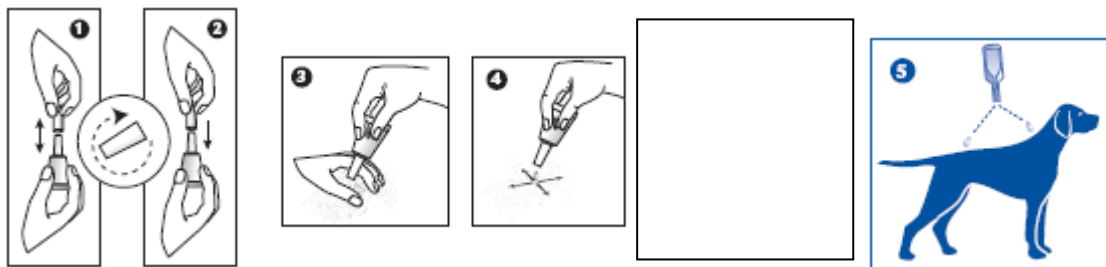
Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the pet's back.



*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 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.

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.

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

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 4.6) may increase in cases of overdose.

**4.11 Withdrawal period**

Not applicable.

**5. PHARMACOLOGICAL PROPERTIES**

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

### **5.1 Pharmacodynamic properties**

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), 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 product is applied, all of the ticks may not be killed within the first 48 hours.

### **5.2 Pharmacokinetic particulars**

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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Butylhydroxyanisole E320  
Butylhydroxytoluene E321  
Benzyl alcohol  
Diethylene glycol monoethyl ether

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale : 18 months.

### **6.4. Special precautions for storage**

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

### **6.5 Nature and composition of immediate packaging**

*Thermoformed pipettes:* White multi-layer plastic single-dose pipettes containing an extractable volume of 0.67 ml.

The internal layers in contact with the product are made of polyacrylonitrile-methacrylate. The white external complex is composed of polypropylene/ cyclic olefine copolymer/ polypropylene.

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

*Polypropylene pipettes:* White polypropylene single-dose pipettes containing an extractible volume of 0.67 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, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product 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.

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

#### **7. MARKETING AUTHORISATION HOLDER**

Virbac S.A.  
1<sup>ère</sup> avenue – 2065 m – L.I.D.  
06516 Carros  
FRANCE  
+ 33 (0)4 92 08 73 04  
+ 33 (0)4 92 08 73 48

#### **8. MARKETING AUTHORISATION NUMBER**

Vm 05653/4151

#### **9. DATE OF FIRST AUTHORISATION**

30 April 2009

#### **10. DATE OF REVISION OF THE TEXT**

30 April 2009

## **SUMMARY OF PRODUCT CHARACTERISTICS** **FOR MEDIUM DOGS**

### **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:**

Butylhydroxyanisole E320    0.268 mg/pipette

Butylhydroxytoluene E321    0.134 mg/pipette

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Spot-on solution.

Clear, colourless to yellow solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs.

#### **4.2 Indications for use**

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 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.

#### **4.3 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, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.

Do not use in cases of hypersensitivity to the active substance or to any of excipients.

#### **4.4 Special warnings for each target species**

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.

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.

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.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.

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

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

Animals should be weighed accurately prior to treatment.

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

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

Do not apply the product on wounds or damaged skin.

##### **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.

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.

Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.

Animals or operators with a known hypersensitivity to fipronil or excipients (see section 6.1.) 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.

#### **Other precautions**

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

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

#### **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 on the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.

#### **4.7 Use during pregnancy and lactation**

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.

#### **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 and dosage:

External use only.

Administer by topical application to the skin according to the bodyweight as follows :

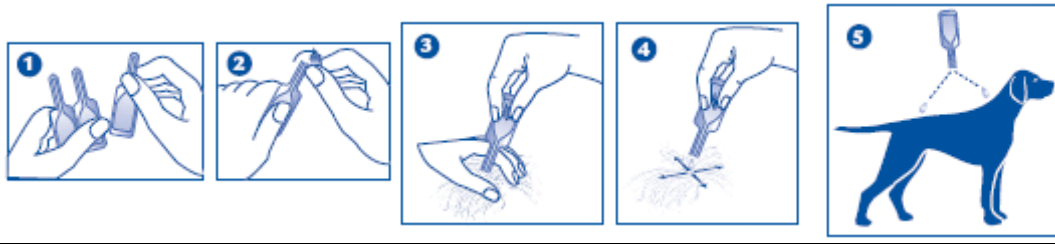
1 pipette of 1.34 ml per dog weighing over 10 kg and up to 20 kg bodyweight.

##### 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.

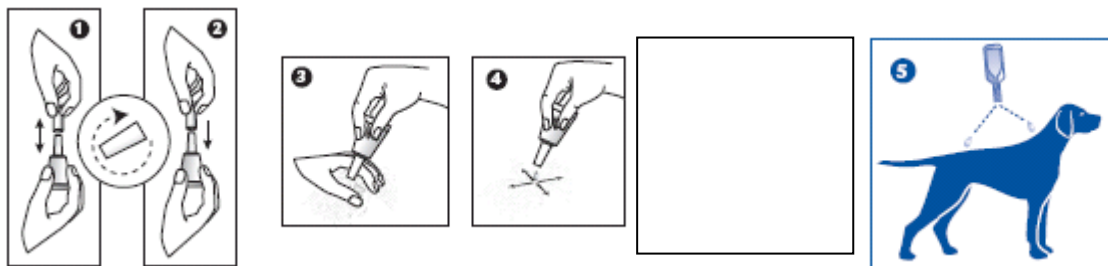
Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the pet's back.



*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 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.

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.

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

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 4.6) may increase in cases of overdose.

**4.11 Withdrawal period**

Not applicable.

## 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Ectoparasiticides for topical use.

ATCvet code: QP53AX15

### 5.1 Pharmacodynamic properties

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), 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 product is applied, all of the ticks may not be killed within the first 48 hours.

### 5.2 Pharmacokinetic particulars

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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Butylhydroxyanisole E320

Butylhydroxytoluene E321

Benzyl alcohol

Diethylene glycol monoethyl ether

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale : 18 months.

### 6.4. Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

*Thermoformed pipettes:* White multi-layer plastic single-dose pipettes containing an extractable volume of 1.34 ml.

The internal layers in contact with the product are made of polyacrylonitrile-methacrylate. The white external complex is composed of polypropylene/ cyclic olefine copolymer/ polypropylene.

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

*Polypropylene pipettes:* White polypropylene single-dose pipettes 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, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product 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.

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

#### **7. MARKETING AUTHORISATION HOLDER**

Virbac S.A.

1<sup>ère</sup> avenue – 2065 m – L.I.D.

06516 Carros

FRANCE

+ 33 (0)4 92 08 73 04

+ 33 (0)4 92 08 73 48

#### **8. MARKETING AUTHORISATION NUMBER(S)**

Vm 05653/4152

#### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

26 November 2008

#### **10. DATE OF REVISION OF THE TEXT**

November 2008

## **SUMMARY OF PRODUCT CHARACTERISTICS** **FOR LARGE DOGS**

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

EFFIPRO 268 mg spot-on solution for large dogs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One 2.68 ml pipette contains :

**Active substance:**

Fipronil 268 mg

**Excipients:**

Butylhydroxyanisole E320 0.536 mg/pipette

Butylhydroxytoluene E321 0.268 mg/pipette

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Spot-on solution.

Clear, colourless to yellow solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs.

#### **4.2 Indications for use**

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 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.

#### **4.3 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, as adverse reactions and even death could occur.  
This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.  
Do not use in cases of hypersensitivity to the active substance or to any of excipients.

#### **4.4 Special warnings for each target species**

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.

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.

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.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.

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

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

Animals should be weighed accurately prior to treatment.

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

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

Do not apply the product on wounds or damaged skin.

##### **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.

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.

Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.

Animals or operators with a known hypersensitivity to fipronil or excipients (see section 6.1.) 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.

### **Other precautions**

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

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

### **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 on the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.

### **4.7 Use during pregnancy and lactation**

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.

### **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 and dosage:

External use only.

Administer by topical application to the skin according to the bodyweight as follows :

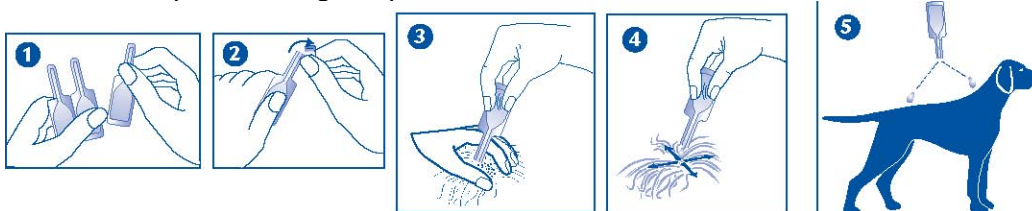
1 pipette of 2.68 ml per dog weighing over 20 kg and up to 40 kg bodyweight.

#### 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.

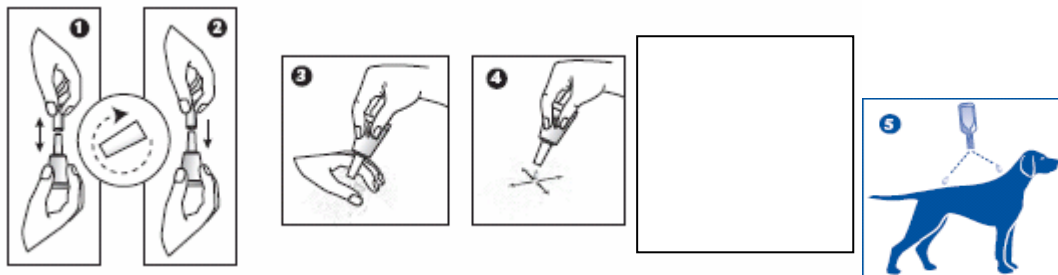
Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents. Repeat this procedure at one or two different points along the pet's back.



**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 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.

**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.

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

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 4.6) may increase in cases of overdose.

#### 4.11 Withdrawal period

Not applicable.

### 5. PHARMACOLOGICAL PROPERTIES

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

#### 5.1 Pharmacodynamic properties

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), 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 product is applied, all of the ticks may not be killed within the first 48 hours.

#### 5.2 Pharmacokinetic particulars

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.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Butylhydroxyanisole E320  
Butylhydroxytoluene E321  
Benzyl alcohol  
Diethylene glycol monoethyl ether

#### 6.2 Incompatibilities

None known.

#### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale : 18 months.

#### 6.4. Special precautions for storage

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

#### 6.5 Nature and composition of immediate packaging

*Thermoformed pipettes:* White multi-layer plastic single-dose pipettes containing an extractible volume of 2.68 ml.

The internal layers in contact with the product are made of polyacrylonitrile-methacrylate. The white external complex is composed of polypropylene/ cyclic olefine copolymer/ polypropylene.

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

*Polypropylene pipettes:* White polypropylene single-dose pipettes containing an extractible volume of 2.68 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, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product 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.

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

### **7. MARKETING AUTHORISATION HOLDER**

Virbac S.A.

1<sup>ère</sup> avenue – 2065 m – L.I.D.

06516 Carros

FRANCE

+ 33 (0)4 92 08 73 04

+ 33 (0)4 92 08 73 48

### **8. MARKETING AUTHORISATION NUMBER**

Vm 05653/4153

### **9. DATE OF FIRST AUTHORISATION**

1 May 2009

### **10. DATE OF REVISION OF THE TEXT**

1 May 2009

## **Summary of Product Characteristics For Very Large Dogs**

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

EFFIPRO 402 mg spot-on solution for very large dogs

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One 4.02 ml pipette contains :

**Active substance:**

Fipronil 402 mg

**Excipients:**

Butylhydroxyanisole E320 0.804 mg/pipette

Butylhydroxytoluene E321 0.402 mg/pipette

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Spot-on solution.

Clear, colourless to yellow solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs.

#### **4.2 Indications for use**

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 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.

#### **4.3 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, as adverse reactions and even death could occur.

This product is specifically developed for dogs. Do not use in cats, as this could lead to overdosing.



Do not use in cases of hypersensitivity to the active substance or to any of excipients.

#### **4.4 Special warnings for each target species**

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.

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.

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.

When used as part of a strategy for the treatment of Flea Allergy Dermatitis, monthly applications to the allergic patient and to other dogs in the household are recommended.

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

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

Animals should be weighed accurately prior to treatment.

Avoid contact with the animal's eyes. In the case of accidental eye contact, immediately and thoroughly flush the eyes with water.

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

Do not apply the product on wounds or damaged skin.

##### **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.

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.

Do not smoke, drink or eat during application.

Avoid contents coming into contact with the fingers. If this occurs, wash hands with soap and water. Wash hands after use.

Animals or operators with a known hypersensitivity to fipronil or excipients (see section 6.1.) 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.

### **Other precautions**

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

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

### **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 on the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use. Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.

### **4.7 Use during pregnancy and lactation**

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.

### **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 and dosage:

External use only.

Administer by topical application to the skin according to the bodyweight as follows :

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

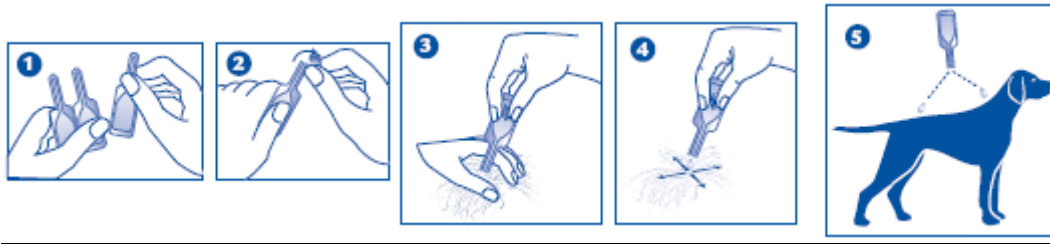
For dogs over 60 kg use two pipettes of 2.68 ml.

#### Method of administration:

##### *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.

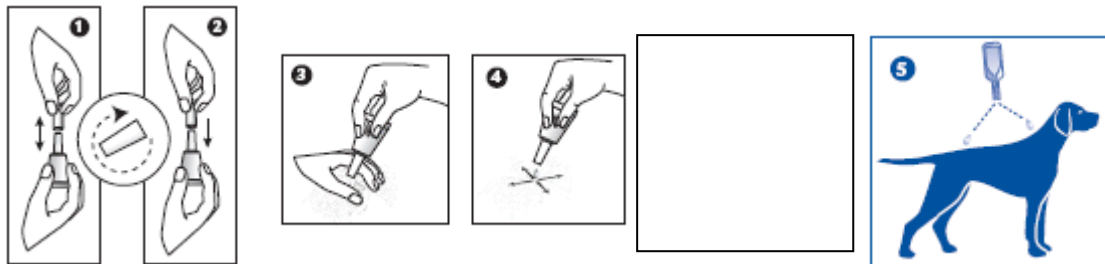
Part the pet's coat until its skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently several times to empty its contents Repeat this procedure at one or two different points along the pet's back.



*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 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.

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.

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

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 4.6) may increase in cases of overdose.

**4.11 Withdrawal period**

Not applicable.

**5. PHARMACOLOGICAL PROPERTIES**

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

### 5.1 Pharmacodynamic properties

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), 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 product is applied, all of the ticks may not be killed within the first 48 hours.

### 5.2 Pharmacokinetic particulars

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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Butylhydroxyanisole E320  
Butylhydroxytoluene E321  
Benzyl alcohol  
Diethylene glycol monoethyl ether

### 6.2 Incompatibilities

None known.

### 6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale : 18 months.

### 6.4. Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

*Thermoformed pipettes:* White multi-layer plastic single-dose pipettes containing an extractable volume of 4.02 ml.

The internal layers in contact with the product are made of polyacrylonitrile-methacrylate. The white external complex is composed of polypropylene/ cyclic olefine copolymer/ polypropylene.

Boxes of 1, 2, 3, 4, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

*Polypropylene pipettes:* White polypropylene single-dose pipettes containing an extractible volume of 4.02 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, 6, 8, 12, 24, 30, 60, 90 or 150 pipettes.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product 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.

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

#### **7. MARKETING AUTHORISATION HOLDER**

Virbac S.A.  
1<sup>ère</sup> avenue – 2065 m – L.I.D.  
06516 Carros  
FRANCE  
+ 33 (0)4 92 08 73 04  
+ 33 (0)4 92 08 73 48

#### **8. MARKETING AUTHORISATION NUMBER**

Vm 05653/4154

#### **9. DATE OF FIRST AUTHORISATION**

1 May 2009

#### **10. DATE OF REVISION OF THE TEXT**

1 May 2009