

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE: CARTON BOX**

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

Fipracyl Spot On Solution 402mg for Extra Large Dogs

### **2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**

Contains: 402mg Fipronil

### **3. PHARMACEUTICAL FORM**

Spot-on solution

### **4. PACKAGE SIZE**

1 pipette, 2\*, 3\*, 4\*, 5\* or 6\* pipettes.

[\*Delete as appropriate]

### **5. TARGET SPECIES**

Dog.

### **6. INDICATION(S)**

Large Dogs Over 40kg

Example Breeds (adult dogs): Bloodhound, Rottweiler, Great Dane

For the treatment of flea (*Ctenocephalides* spp.) and tick (*Rhipicephalus sanguineus* and *Ixodes ricinus*) infestations.

Fipracyl has a persistent insecticidal efficacy for up to 8 weeks against fleas (*Ctenocephalides* spp.) and a persistent acaricidal efficacy for up to 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus* and *Dermacentor reticulatus*).

If ticks of some species (*Dermacentor reticulatus*) are already present when the product is applied, all of the ticks may not be killed within the first 48 hours.

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.

### **7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For external use only.

Animals should be weighed accurately prior to treatment.

One pipette per dog of 40 – 60kg.

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

Please read the package leaflet before use for full instructions, including user warnings.

Do not use on rabbits!



1. Remove the pipette from the blister packaging. Hold the pipette in an upright position and snap off the top section of the cap, thereby opening the pipette.
2. Part your dog's coat until the skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently. Empty approximately half the contents at each of two points along the dog's back, preferably at the base of the head and between the shoulder blades. Squeeze the pipette several times to ensure dosing is complete. Avoid applying the solution onto the fur and do not rub into the skin.
3. Application of the solution as directed minimises the possibility that the animal will lick the solution off. Do not allow pets to lick each other after treatment.

## 8. WITHDRAWAL PERIOD

## 9. SPECIAL WARNING(S), IF NECESSARY

Please read the package leaflet before use for full instructions, including user warnings.

## 10. EXPIRY DATE

EXP: end {month/year}

## 11. SPECIAL STORAGE CONDITIONS

Store below 25 °C, in in a dry place in the original packaging.

## 12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements. Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

For animal treatment only.

*[Distribution category]*

NFA-VPS

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

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Bob Martin UK Ltd.  
Wemberham Lane  
Yatton  
North Somerset  
BS49 4BS

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

Vm 00715/4128

**17. MANUFACTURER’S BATCH NUMBER**

Batch no: {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**  
**UNITS : PIPETTE LABEL**

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

Fipracyl Spot On Solution 402 mg For Extra Large Dogs

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

402 mg

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

4.02 ml

**4. ROUTE(S) OF ADMINISTRATION**

Spot on

**5. WITHDRAWAL PERIOD**

**6. BATCH NUMBER**

Batch no: {number}

**7. EXPIRY DATE**

EXP end {month/year}

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

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS: PVC  
BLISTER WITH FOIL SEAL**

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

Fipracyl Spot On Solution 402mg for extra large dogs

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

Bob Martin UK Ltd.

**3. EXPIRY DATE**

EXP end {month/year}

**4. BATCH NUMBER**

Batch No. {number}

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

For animal treatment only.

## **PACKAGE LEAFLET**

### **1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Bob Martin UK Ltd.  
Wemberham Lane,  
Yatton,  
North Somerset,  
BS49 4BS,  
UK

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

Fipracyl Spot On Solution for dogs

For small, medium, large and extra large dogs

### **3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS**

| <b>Dog</b>                                      | <b>Weight (kg)</b> | <b>Unit dose</b> | <b>Fipronil</b> | <b>Excipients: Butylhydroxanisole</b> | <b>Excipients: Butylhydroxytoluene</b> |
|---|--------------------|------------------|-----------------|---------------------------------------|--|
| Fipracyl Spot On Solution 67mg for Small Dogs   | 2 - 10             | 0.67 ml          | 67 mg           | 0.134 mg/pipette                      | 0.067 mg/ pipette                      |
| Fipracyl Spot On Solution 134mg for Medium Dogs | 10-20              | 1.34 ml          | 134 mg          | 0.268 mg/ pipette                     | 0.134 mg/ pipette                      |
| Fipracyl Spot On Solution 268mg for Large Dogs  | 20-40              | 2.68 ml          | 268 mg          | 0.536 mg/ pipette                     | 0.268 mg/ pipette                      |
| Fipracyl Spot On Solution 402mg for             | 40-60              | 4.02 ml          | 402 mg          | 0.804 mg/ pipette                     | 0.402 mg/ pipette                      |

|                  |  |  |  |  |  |
|------------------|--|--|--|--|--|
| Extra Large Dogs |  |  |  |  |  |
|------------------|--|--|--|--|--|

#### **4. INDICATION(S)**

Treatment of flea (*Ctenocephalides* spp.) and tick (*Rhipicephalus sanguineus* and *Ixodes ricinus*) infestations.

Fipracyl has a persistent insecticidal efficacy for up to 8 weeks against fleas (*Ctenocephalides* spp.) and a persistent acaricidal efficacy for up to 4 weeks against ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus* and *Dermacentor reticulatus*).

If ticks of some species (*Dermacentor reticulatus*) are already present when the product is applied, all of the ticks may not be killed within the first 48 hours.

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.

#### **5. CONTRAINDICATIONS**

Do not use on puppies less than 2 months old and/or weighing less than 2kg for small dogs, 10kg for medium dogs, 20kg for large dogs and 40kg for extra large dogs, respectively.

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 on animals with known hypersensitivity to the active substance or to any of the excipients.

#### **6. ADVERSE REACTIONS**

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.

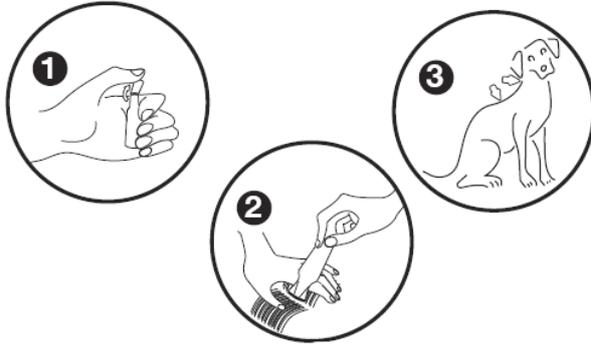
#### **7. TARGET SPECIES**

Dog.

#### **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

External use only. Administer by topical application to the skin 1 pipette per animal, or if over 60kg, 2 pipettes of 2.68ml.

Do not use on rabbits!



Remove the pipette from the blister packaging. Hold the pipette in an upright position and snap off the top section of the cap, thereby opening the pipette.

Part your dog's coat until the skin is visible. Place the tip of the pipette directly against the bared skin and squeeze gently. Empty approximately half the contents at each of two points along the dog's back, preferably at the base of the head and between the shoulder blades. Squeeze the pipette several times to ensure dosing is complete. Avoid applying the solution onto the fur and do not rub into the skin.

## 9. ADVICE ON CORRECT ADMINISTRATION

Application of the solution as directed minimises the possibility that the animal will lick the solution off. Do not allow pets to lick each other after 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 usually disappear within 24-48 hours post application. Crystals may be seen on the hair and slight scaling may occur within 24-48 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.

The minimum interval between two treatments is 4 weeks.

## 10. WITHDRAWAL PERIOD(S)

Not applicable

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

Store below 25 °C, in a dry place in the original packaging.

## **12. SPECIAL WARNING(S)**

Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of the product in these cases has not been tested.

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 twist.

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.

When treating infestations, all in-contact dogs should be treated with an appropriate product at the same time.

### **Special precautions for use**

#### **i) 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 allow pets to lick each other after treatment

Do not apply the product on wounds or damaged skin.

#### **ii) 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 people with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the 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.

### **iii) Environmental warning**

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

### **iv) Other precautions**

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

### **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.

### **Interaction with other medicinal products and other forms of interaction**

None known.

### **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 5 times the therapeutic dose once a month for 3 consecutive months. The risk of adverse effects (see section 6) may increase in cases of overdose.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

March 2013

**15. OTHER INFORMATION**

Blister cards or boxes of 1, 2, 3, 4, 5 or 6 pipettes.

Not all pack sizes may be marketed.

Distribution category:

NFA-VPS

Vm 00715/4128

For animal treatment only.

**Approved: 09/08/2017**

A handwritten signature in black ink, appearing to read 'J. Long', is written below the approval date.