

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

### **CARTON BOX**

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

Bob Martin Clear Spot on 50 mg spot-on solution for cats  
UK: Bob Martin Fipronil 50 mg spot-on solution for cats

Fipronil

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

Contains: 50mg 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**

Cat

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

Fleas will be killed within 24 h. The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides spp.*).

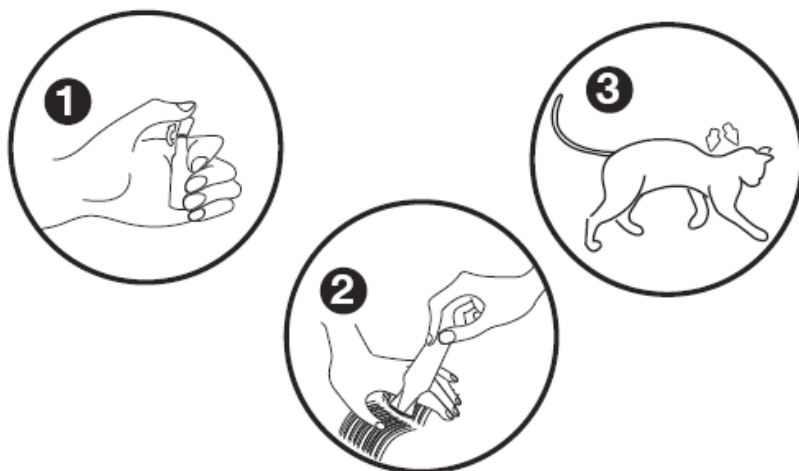
Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy against *Dermacentor reticulatus*. If ticks of this species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they will be killed 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.

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

For external use only.  
Apply one pipette per cat

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



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 the pet's coat until the skin is visible. Place the tip of the tube directly against the bared skin and squeeze gently. Empty approximately half the contents at two points along the cat's back. The first application point is at the base of the head and the second application point is between the shoulder blades. Squeeze the tube 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.

The minimum interval between two treatments is 4 weeks.

## **8. WITHDRAWAL PERIOD**

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

Read the package leaflet before use.

Do not use on cats that are less than 2 months old and/or weight less than 1kg.

Do not use on rabbits.

Do not use on animals with known hypersensitivity to the active substance or to any of the other ingredients.

## **10. EXPIRY DATE**

EXP: end {month/year}

## **11. SPECIAL STORAGE CONDITIONS**

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

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Dispose of waste materials 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.  
For external use only.

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

Keep out of the sight and reach of children.

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

Pets Choice Limited  
Brentwood House  
Lower Philips Road  
Whitebirk Industrial Estate  
Blackburn  
Lancashire  
BB1 5UD  
United Kingdom

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

Vm 52797/3009

**17. MANUFACTURER'S BATCH NUMBER**

Batch no: {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**PVC BLISTER WITH FOIL SEAL**

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

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Fipronil

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

Pets Choice Limited  
Brentwood House  
Lower Philips Road  
Whitebirk Industrial Estate  
Blackburn  
Lancashire  
BB1 5UD  
United Kingdom

**3. EXPIRY DATE**

EXP: end {month/year}

**4. BATCH NUMBER**

Batch No. {number}

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

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**PIPETTE LABEL**

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

Bob Martin Clear Spot on 50 mg spot-on solution for cats  
UK: Bob Martin Fipronil 50 mg spot-on solution for cats

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

50 mg

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

N/A – single dose pipette

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

Spot-on

**5. WITHDRAWAL PERIOD**

N/A – companion animal target species

**6. BATCH NUMBER**

Batch no: {number}

**7. EXPIRY DATE**

EXP: end {month/year}

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

For animal treatment only.

## **PACKAGE LEAFLET**

### **Bob Martin Clear Spot on 50 mg spot-on solution for cats**

UK: Bob Martin Fipronil 50 mg spot-on solution for cats

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

Marketing authorisation holder:

Pets Choice Limited  
Brentwood House  
Lower Philips Road  
Whitebirk Industrial Estate  
Blackburn  
Lancashire  
BB1 5UD  
United Kingdom

Manufacture for batch release:

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

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

Bob Martin Clear Spot on 50 mg spot-on solution for cats  
UK: Bob Martin Fipronil 50 mg spot-on solution for cats  
Fipronil

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

One 0.50 ml pipette contains:

**Active substance:**

Fipronil 50 mg

**Excipients:**

Butylhydroxyanisole E320 0.100 mg

Butylhydroxytoluene E321 0.050 mg

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

Treatment of flea (*Ctenocephalides spp.*) infestations.

Fleas will be killed within 24 h. The product has a persistent insecticidal efficacy for up to 5 weeks against fleas (*Ctenocephalides spp.*).

Although no immediate killing effect against ticks has been demonstrated, the product has shown an acaricidal efficacy against *Dermacentor reticulatus*. If ticks of

this species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they will 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.

## 5. CONTRAINDICATIONS

Do not use 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 on animals with known hypersensitivity to the active substance or to any of excipients.

## 6. ADVERSE REACTIONS

If licking occurs, a brief period of hypersalivation may be observed due mainly to the nature of the carrier.

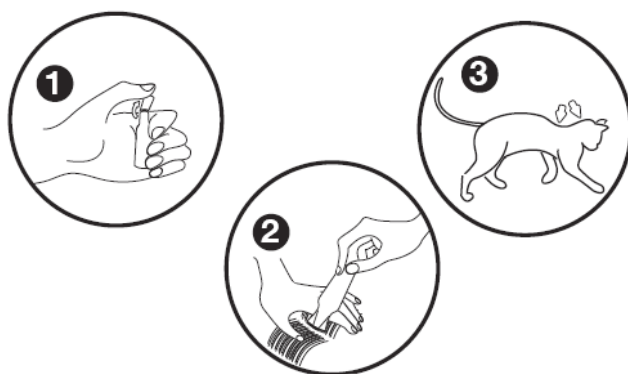
Among the extremely rare suspected adverse reactions, transient cutaneous reactions on the application site (skin discoloration, local alopecia, pruritus, erythema) and general pruritus or alopecia have been reported after use.  
Exceptionally, hypersalivation, reversible neurologic symptoms (hyperesthesia, depression, nervous symptoms), vomiting or respiratory symptoms have been observed after use.

## 7. TARGET SPECIES

Cat.

## 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.



Remove the pipette from the blister packaging. Hold the pipette upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Twist and pull the snap-off top of the pipette to enable the contents to be expelled.

Part the pet's coat until the skin is visible. Place the tip of the tube directly against the bared skin and squeeze gently. Empty approximately half the contents at two points along the cat's back. The first application point is at the base of the head and the second application point is between the shoulder blades. Squeeze the tube 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 infestation the treatment schedule can be based on the local epidemiological situation.

The minimum interval between two treatments is 4 weeks

## **10. WITHDRAWAL PERIOD**

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

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

## **12. SPECIAL WARNINGS**

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.

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

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.

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

### **Special precautions for use**

#### **i) 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.

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.

**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.

Keep pipettes in the original packaging and dispose of used pipettes immediately.

**iii) Other precautions**

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

**iv) 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 cats. Use in pregnancy and lactation only in accordance with professional veterinary advice and a benefit/risk assessment.

**v) Overdose**

The toxicity of the veterinary medicinal product when administered to the skin is very low. The risk of experiencing adverse effects may increase in cases of over-dose, so animals should always be treated with the correct product according to species and bodyweight.

No adverse effects were observed in a target animal safety study in eight weeks-old cats weighing about 1 kg treated with 5 times the therapeutic dose monthly for three months.

**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 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.

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

**15. OTHER INFORMATION**

Blister cards or boxes of 1, 2, 3, 4, 5 or 6 pipettes.  
Not all pack sizes may be marketed.

MARKETING AUTHORISATION NUMBER(S)

Vm 52797/3009

For animal treatment only

Approved 09 July 2021

A handwritten signature in black ink, appearing to read 'A. Hunter.', is positioned below the approval date.