

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

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON BOX or BLISTER CARD**

**For external use only. Small dogs 2-10kg**

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

Bob Martin Clear Plus 67 mg/ 60.3 mg Spot-on Solution for Small Dogs  
Fipronil  
(S)-methoprene

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each pipette contains 67 mg Fipronil and 60.3 mg (S)-methoprene.

**3. PHARMACEUTICAL FORM**

Spot-on solution.

**4. PACKAGE SIZE**

1 pipette  
2 pipettes  
3 pipettes  
4 pipettes  
5 pipettes  
6 pipettes

**5. TARGET SPECIES**

For small dogs.

**6. INDICATION(S)**

Flea & tick  
Treat and protect  
Kills fleas for 8 weeks  
Kills ticks for 4 weeks  
Kills flea eggs for 8 weeks  
Kills fleas and ticks, as well as biting lice  
Each treatment kills fleas within 24 hours and for up to 8 weeks, and ticks within 48 hours and for up to 4 weeks.  
It contains Fipronil plus (S)-methoprene, an insect growth regulator, which inhibits the development of flea eggs, larvae and pupae for up to 8 weeks after application, preventing re-infestation of the pet's home environment.

Small dogs 2-10 kg and over 8 weeks old. Example breeds small (adult) dogs 2-10kg: West Highland Terrier, Yorkshire Terrier, Jack Russell, King Charles Spaniel.

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

### Directions for use:

Weigh the dog first and ensure that the correct product is used based on the weight of the dog detailed on the front of the pack purchased.

### Thermoformed pipettes:

#### STEP 1

Bob Martin Clear Plus must be applied at 2 points, at the base of the back of the dog's head and between the shoulder blades. If the dog is wearing a collar, remove it first so that it does not restrict application.



#### STEP 2

Remove a single pipette from the pack. Hold the pipette upright and allow any liquid in the neck of the pipette to drain into the main body. Continue holding the pipette upright and snap off the tip.



#### STEP 3

Part your dog's coat until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently. Apply approximately half the pipette at one point and half at the second point. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance.



### Polypropylene pipettes

Weigh the dog first and ensure that the correct product is used based on the weight of the dog detailed on the front of the pack purchased.



1. Bob Martin Clear Plus must be applied at 2 points – at the base of the back of the head and between the shoulder blades. If the dog is wearing a collar remove it first so that it does not restrict application.
2. Remove a single pipette from the pack. Hold pipette upright and snap off the top section of the cap opening the pipette.
3. Part your dog's coat until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently. Apply approximately half of the pipette at one point and half at the second point. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance.

**Apply to an area where the animal cannot lick it off and do not allow pets to lick each other after treatment.**

Regular treatment of all cats and dogs in the home, together with regular vacuuming of your pet's bedding and resting areas, is needed to protect your pet and home from fleas. If there is an existing and heavy infestation in your home, it may also be necessary to treat the home with an approved home flea product.

### **8. WITHDRAWAL PERIOD(S)**

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



**Do not use on rabbits as may cause death!**

Do not use if you know your pet has a known hypersensitivity to Fipronil or any other ingredient.

**Read the enclosed package leaflet before use for full instructions and all warnings, including user warnings. The directions for use and user safety warnings can also be found on the inner flap of the carton and should be read before each use.**

**USER SAFETY- Please read before every use**

Keep pipettes in original packaging until ready to use.

This product can cause mucous membrane, skin and eye irritation. Do not get the product on your skin or in your eyes or mouth.

If skin contact does occur wash it off quickly and thoroughly with soap and water. In case of accidental eye contact, immediately and thoroughly flush the eyes with clean water. If the eye irritation continues, seek medical advice and show the package leaflet or the packaging to the doctor.

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with this product.

Wash hands after use.

Treated animals should not be handled or played with until the application site has dried. Therefore, evening application is recommended. Treated pets should not be allowed to sleep with owners, especially children.

Do not smoke, drink or eat whilst using this product.

**10. EXPIRY DATE**

EXP: end {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Do not store above 25°C.

Store in a dry place and in the original package.

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

Dispose of waste material in accordance with local requirements. Fipronil and (S)-Methoprene should not enter water courses as this may be dangerous for fish or other aquatic organisms.

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

For animal treatment 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 Ltd  
Brentwood House  
Lower Philips Road  
Whitebirk Industrial Estate  
Blackburn  
Lancashire  
BB1 5UD  
UK

**16. MARKETING AUTHORISATION NUMBER**

Vm 52797/4011

**17. MANUFACTURER’S BATCH NUMBER**

Batch No: {number}

**Other Information**

Made by Pet’s Choice Limited in the UK under license from Martin & Martin Holdings  
Bob Martin is a registered trade mark of Martin & Martin Holdings.

Since 1892 Bob Martin has provided vet-quality healthcare solutions for happy, healthy pets.

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

**PIPETTE LABEL**

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

Bob Martin Clear Plus 67 mg/ 60.3 mg Spot-on Solution for Small Dogs  
Fipronil  
(S)-methoprene

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

67 mg/60.3 mg

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

67 mg/60.3 mg

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

Spot-on

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Batch No: {number}

**7. EXPIRY DATE**

EXP {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**

Bob Martin Clear Plus 67 mg/ 60.3 mg Spot-on Solution for Small Dogs  
Fipronil  
(S)-methoprene

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

Pets Choice Limited

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Batch No {number}

**5. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET:

Bob Martin Clear Plus 67 mg/ 60.3 mg Spot-on Solution for Small Dogs  
Bob Martin Clear Plus 134 mg/ 120.6 mg Spot-on Solution for Medium Dogs  
Bob Martin Clear Plus 268 mg/ 241.2 mg Spot-on Solution for Large Dogs

### **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 Ltd  
Brentwood House  
Lower Philips Road  
Whitebirk Industrial Estate  
Blackburn  
Lancashire  
BB1 5UD  
UK

Manufacturer responsible for batch release:

Pets Choice Ltd  
8 Wemberham Lane  
Yatton  
North Somerset  
BS49 4BS  
United Kingdom

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

Bob Martin Clear Plus 67 mg/ 60.3 mg Spot-on Solution for Small Dogs  
Bob Martin Clear Plus 134 mg/ 120.6 mg Spot-on Solution for Medium Dogs  
Bob Martin Clear Plus 268 mg/ 241.2 mg Spot-on Solution for Large Dogs

Fipronil  
(S)-methoprene

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

Clear amber solution.

Product	Dog Size	Treatment	Contents			
			Active Substance		Excipients (other ingredients)	
			Fipronil	(S)-methoprene	Butylhydroxyanisole (E320)	Butylhydroxytoluene (E321)
Bob Martin Clear Plus 67 mg/ 60.3 mg Spot-on Solution for Small Dogs	Min 2kg up to 10kg	Use one 0.67 ml pipette	67 mg	60.3 mg	0.134 mg	0.067 mg
Bob Martin Clear Plus 134 mg/ 120.6 mg Spot-on Solution for Medium Dogs	>10kg up to 20kg	Use one 1.34 ml pipette	134 mg	120.6 mg	0.268 mg	0.134 mg
Bob Martin Clear Plus 268 mg/ 241.2 mg Spot-on Solution for Large Dogs	> 20kg up to 40kg	Use one 2.68 ml pipette	268 mg	241.2 mg	0.536 mg	0.268 mg

#### 4. INDICATION(S)

Flea & tick treat & protect  
Kills fleas fast  
Kills ticks  
Kills flea eggs

Bob Martin Clear Plus for dogs is for killing fleas and ticks on your dog and treatment of infestations with biting lice. Each treatment kills fleas within 24 hours and for up to 8 weeks, and ticks within 48 hours and for up to 4 weeks. provides protection against fleas for up to 8 weeks and protects from ticks by up to 4 weeks.

Inhibits the development of flea eggs, larvae and pupae for 8 weeks after application preventing re-infestation of the dog's home environment.

Bob Martin Clear Plus can be used on dogs over 8 weeks old.

#### 5. CONTRAINDICATIONS

Do not use this product on puppies less than 8 weeks old

Do not use in dogs weighing less than the minimum weight specified on the package.

Do not use on unwell animals or animals recovering from an illness or operation.

**Do not use in rabbits, as adverse reactions or even death could occur.** In the absence of studies, the use of the product is not recommended in species other than dogs.

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

Do not use in animals known to be allergic to the active substances (Fipronil and (S)-methoprene) or to any of the other ingredients (excipients).

## **6. ADVERSE REACTIONS**

Among the very rare suspected adverse reactions, temporary skin reactions on the application site (skin discoloration, local hair loss, itching, redness) and general itching or hair loss have been reported after use. Excessive salivation, reversible nervous signs (increased sensitivity to stimulation, depression, other nervous signs), vomiting or respiratory symptoms have also been observed after use.

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

## **7. TARGET SPECIES**

Dogs.

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

Use one pipette per dog, applied to the skin as directed.

## **9. ADVICE ON CORRECT ADMINISTRATION**

**For external use only.**

**To safeguard your health and that of your dog please read this leaflet carefully before you apply the product to your dog.**

**How should I use Bob Martin Clear Plus?**

Check that your dog is at least 8 weeks old AND that their weight falls within the weight range detailed on the front of the pack purchased.

**Weigh the dog first** and ensure that correct product is used for the weight of the dog.

Thermoformed pipettes:

1. Bob Martin Clear Plus must be applied at 2 points, at the base of the back of the dog's head and between the shoulder blades. If the dog is wearing a collar, remove it first so that it does not restrict application.



2. Remove a single pipette from the pack. Hold the pipette upright and allow any liquid in the neck of the pipette to drain into the main body. Continue holding the pipette upright and snap off the tip.



3. Part your dog's coat until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently. Apply approximately half the pipette at one point and half at the second point



Polypropylene pipettes



1. Bob Martin Clear Plus must be applied at 2 points – at the base of the back of the dog's head and between the shoulder blades. If the dog is wearing a collar remove it first so that it does not restrict application.
2. Remove a single pipette from the pack. Hold the pipette upright and snap off the top section of the cap opening the pipette.
3. Part your dog's coat until the skin is visible. Place the tip of the pipette directly against the skin and squeeze gently. Apply approximately half the pipette at one point and half at the second point. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance.

**Apply to an area where the animal cannot lick it off and do not allow pets to lick each other following treatment.**

Temporary changes to the coat (clumped/greasy hair) may be noted at the application site.

Avoid swimming or bathing the dog for at least two days.  
Avoid frequent shampooing or swimming

### **Is Bob Martin Clear Plus all I need?**

Regular treatment of all cats, ferrets and dogs in the home together with regular vacuuming of your pet's bedding and resting areas is needed to protect your pet and home from fleas. If there is an existing and heavy infestation in the home it may also be necessary to treat the home with an approved home flea product. When treating infestations of parasites, all in-contact animals should be treated with an appropriate product at the same time.

### **How often should I use Bob Martin Clear Plus?**

This product provides protection from fleas for 8 weeks, ticks for 4 weeks. The minimum interval between treatments is 4 weeks.

## **10. WITHDRAWAL PERIOD(S)**

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in a dry place and in the original package.

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

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

### Special warnings in the target species

There may be an attachment of single ticks. For this reason a transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.

### Special precautions for use in animals

For animal treatment only.

Take care to ensure that the liquid in the pipette does not come into contact with the pet's eye or mouth. If it does come into contact, wash it off quickly and thoroughly. If necessary seek veterinary advice.

Only apply the product as instructed so that your pet cannot lick it off.

Do not allow recently treated pets to groom each other.

Do not apply to any area of your dog's skin that is damaged (scratched, reddened, broken).

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

Keep pipettes in original packaging until ready to use.

This product can cause mucous membrane, skin and eye irritation. Do not get the product on your skin or in your eyes or mouth.

If skin contact does occur wash it off quickly and thoroughly with soap and water. In case of accidental eye contact, immediately and thoroughly flush the eyes with clean water. If the eye irritation continues, seek medical advice and show the package leaflet or the packaging to the doctor.

If the product is accidentally swallowed, seek medical advice immediately and show the package leaflet to the physician.

People with a known hypersensitivity (allergy) to insecticides or alcohol should avoid contact with this product.

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

Wash hands after use.

Treated animals should not be handled or played with until the application site has dried. Therefore, evening application is recommended. Treated dogs should not be allowed to sleep with owners, especially children.

Do not smoke, drink or eat whilst using this product.



Pregnancy and lactation:

Not recommended for use in pregnant and nursing dogs. Consult your veterinary surgeon for advice.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously at the same time as other flea products which are applied directly onto the dog's skin.

Overdose (symptoms, emergency procedures, antidotes):

No adverse effects were observed in target animal safety studies in 8 week-old puppies, growing dogs and dogs weighing about 2 kg treated once at five times the recommended dose. The risk of experiencing adverse effects may however increase when overdosing, so animals should always be treated with the correct pipette size according to bodyweight.

Other precautions:

Dogs should not be allowed to swim in water courses for 2 days after application.

This product may mark certain materials including leather, fabrics, plastics and finished surfaces. Allow application site to dry before permitting contact with these materials.

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

Dispose of waste material in accordance with local requirements. Fipronil and (S)-methoprene should not enter water courses as this may be dangerous for fish or other aquatic organisms.

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

June 2023

**15. OTHER INFORMATION**

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

Not all pack sizes may be marketed.



Approved: 12 June 2023