

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTON BOX/BLISTER CARD**

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

Bob Martin Clear Spot On Solution 402 mg for Extra Large Dogs

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

Contains: Fipronil  
Each pipette contains 402 mg fipronil

**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)**

Example breeds extra large (adult) dogs over 40 kg: Bloodhound, Rottweiler, Great Dane.

Clear Spot On Solution 402 mg for extra large dogs is for killing fleas and ticks on your dogs. Applied at the back of the neck and between the shoulders, each treatment provides protection against fleas for up to 8 weeks and protects from ticks by up to 4 weeks.

Bob Martin Clear Spot On can be used on dogs over 2 months old and is suitable for use in homes with both cats and dogs.

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

Directions for use:  
For external use only.

Weigh the puppy first and ensure that the correct product is used based on the weight of the puppy. This pack would treat a puppy weighing over 40 kg.



1. Clear Spot On 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 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 of the pipette at one point and half at the second point. Squeeze the pipette several times to ensure dosing is complete. Avoid applying onto the fur and do not rub into the skin as this will reduce the product's performance. 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 the home it may also be necessary to treat the home with an approved home flea product.

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

## 8. WITHDRAWAL PERIOD

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



**Do not use on rabbits!**

Do not use this product on puppies of less than 2 months of age.  
Do not use on puppies weighing less than 40 kg.

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.

This product can cause mucous membrane 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 eye irritation continues seek medical advice and show the package leaflet or the packaging to the doctor.

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

Wash hands thoroughly after use.

People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the veterinary medicinal product.

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

#### **10. EXPIRY DATE**

EXP {month/year}

#### **11. SPECIAL STORAGE CONDITIONS**

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

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

Fipronil may adversely affect aquatic organisms. Dispose of waste materials in accordance with local requirements.

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

**16. MARKETING AUTHORISATION NUMBER**

Vm 52797/3002

**17. MANUFACTURER'S BATCH NUMBER**

<Batch> {number}

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

**PIPETTE LABEL**

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

Bob Martin Clear 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**

402 mg

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

Spot on

**5. WITHDRAWAL PERIOD**

N/A

**6. BATCH NUMBER**

Batch No: {number}

**7. EXPIRY DATE**

EXP:

**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 Spot On Solution 402 mg for Extra Large Dogs  
fipronil

**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 FOR:**

**Bob Martin Clear Spot On Solution 402 mg for Extra 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 Limited  
Brentwood House  
Lower Philips Road  
Whitebirk Industrial Estate  
Blackburn  
Lancashire  
BB1 5UD  
United Kingdom

Manufacturer responsible for batch release:

Baggerman Farmanet N.V.  
Barrierweg 3 G  
Eindhoven  
5622CL  
Netherlands

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

Bob Martin Clear Spot On Solution 402 mg for Extra Large Dogs

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

Clear, pale amber solution.

Product	Dog Size	Treatment	Contents		
			Active Substance	Excipients (other ingredients)	
			Fipronil	Butylhydroxyanisole (E320)	Butylhydroxytoluene (E321)
Bob Martin Clear Spot On Solution 67 mg for Small Dogs	2-10 kg	Use one 0.67 ml pipette	67 mg	0.134 mg	0.067 mg
Bob Martin Clear Spot On Solution 134 mg for Medium Dogs	10-20 kg	Use one 1.34 ml pipette	134 mg	0.268 mg	0.134 mg
Bob Martin Clear Spot On Solution 268 mg for Large Dogs	20-40 kg	Use one 2.68 ml pipette	268 mg	0.536 mg	0.268 mg
Bob Martin Clear Spot On Solution 402 mg for Extra Large Dogs	40-60 kg	Use one 4.02 ml pipette	402 mg	0.804 mg	0.402 mg

#### 4. INDICATION(S)

Bob Martin Clear Spot On Solution for dogs is for killing fleas and ticks on your dog. Applied at the back of the neck and between the shoulders, each treatment provides protection against fleas for up to 8 weeks and protects from ticks by up to 4 weeks. Kills fleas and is clinically proven to be effective in 48 hours. This product does not prevent ticks from attaching to dogs but will kill ticks within 48 hours.

Bob Martin Clear Spot On can be used on dogs over 2 months old and is suitable for use in homes with both cats and dogs.

#### 5. CONTRAINDICATIONS

Do not use this product on puppies less than 2 months old or weighing less than 2 kg.

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

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



Do not use on rabbits as death may occur!

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

Do not use on sick or convalescent animals.

#### 6. ADVERSE REACTIONS

The product tastes extremely bitter and could make a dog salivate (drool) if the treated dog or another pet were to lick the skin soon after application. The drooling will usually disappear after a short while.

In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur either where the product was applied or more widely across the animal. Excessive salivation and nervous signs such as depression, hypersensitivity, vomiting or heavy breathing have been reported exceptionally.

## 7. TARGET SPECIES

For dogs

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

Use one pipette per dog, applied to the skin as directed.  
For dogs over 60 kg use two pipettes 268 mg Fipronil (Bob Martin Clear Spot On Solution 268 mg for Large Dogs)

## 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 Spot On?

Check that your dog is at least 2 months old AND that their weight falls within the weight range detailed on the front of the pack purchased.

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



1. Clear Spot On 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 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 of the pipette at one point and half at the second point. Squeeze the pipette several times to ensure dosing is complete. Avoid applying onto the fur and do not rub into the skin as this

will reduce the product's performance. Do not allow pets to lick each other after treatment.

Avoid excessive wetting of the hair; occasionally some stickiness of crystals are be seen but these will usually disappear within 48 hours.

Avoid frequent shampooing or swimming

### **Is clear spot on all I need?**

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 the home it may also be necessary to treat the home with an approved home flea product.

### **How often should I use Clear Spot On?**

This product provides protection from fleas for 8 weeks and ticks for 4 weeks. The minimum interval between 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 and in the original packaging.

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 precautions for use in animals

Do not allow recently treated pets to groom each other.

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

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

### Pregnancy and lactation

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

If signs of disease persist or appear, consult a veterinary surgeon.

### Overdose

The safety of this product has not been investigated in studies where overdose or repeated dosing were used due to the well-known safety profile of the active substance and other ingredients.

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

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.

This product can cause mucous membrane 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 eye irritation continues seek medical advice and show the package leaflet or the packaging to the doctor.

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

Wash hands thoroughly after use.

People with a known hypersensitivity to fipronil or any of the other ingredients should avoid contact with the veterinary medicinal product.

For animal treatment only.

Other precautions

Fipronil may adversely affect aquatic organisms. 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**

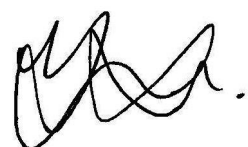
Dispose of empty packaging and any remaining product in accordance with local requirements. Fipronil may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty container.

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

February 2024

**15. OTHER INFORMATION**

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



Approved: 04 May 2024