

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX or BLISTER CARD

For external use only. For dogs weighing greater than 40 kg up to a maximum of 60 kg.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Plus 402 mg/ 361.8 mg Spot-On Solution for Extra Large Dogs
fipronil
(S)-methoprene

2. STATEMENT OF ACTIVE SUBSTANCES

Each pipette contains 402 mg fipronil and 361.8 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 extra large dogs.

6. INDICATION(S)

Kills fleas and ticks
Kills fleas for 8 weeks
Kills ticks for 4 weeks
Kills biting lice
Inhibits the development of flea eggs, larvae and pupae for 8 weeks after application preventing the re-infestation of the dog's home environment.
Inhibits the development of flea eggs and larvae
Contains S-methoprene, an insect growth regulator.

For dogs weighing greater than 40 kg up to 60 kg and over 8 weeks old.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions for use:

For external use only.

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.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

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

Read the enclosed package leaflet before use for full instructions 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.

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.

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

10. EXPIRY DATE

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

16. MARKETING AUTHORISATION NUMBER

Vm 52797/4014

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

Bob Martin Clear Plus 402 mg/ 361.8 mg Spot-On Solution for Extra Large Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

402 mg/361.8 mg

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

402 mg/361.8 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 402 mg/ 361.8 mg Spot-On Solution for Extra Large 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
Bob Martin Clear Plus 402 mg/ 361.8 mg Spot-On Solution 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:

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
Bob Martin Clear Plus 402 mg/ 361.8 mg Spot-On Solution for Extra 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	Minimum of 2 up to a maximum of 10 kg	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	Greater than 10 up to maximum of -20 kg	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	Greater than 20 up to a maximum of -40 kg	Use one 2.68 ml pipette	268 mg	241.2 mg	0.536 mg	0.268 mg
Bob Martin Clear Plus 402 mg/ 361.8 mg Spot-On Solution for Extra Large Dogs	Greater than 40 up to a maximum of -60 kg	Use one 4.02 ml pipette	402 mg	361.8 mg	0.804 mg	0.402 mg

4. INDICATION(S)

Bob Martin Clear Plus for dogs is for killing fleas and ticks on your dog and treatment of infestations with biting lice. Each treatment 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.



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.

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 2 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.

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.

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:

Fipronil and (S)-methoprene 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 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

April 2021

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 22 June 2023

