

ANNEX III
LABELLING

A. LABELLING

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 Healthcare Limited

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Batch No {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO
PACKAGE LEAFLET, Carton Box/Blister card**

**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 Healthcare Limited
38 Main Street
Swords
Dublin
K67E 0A2
Ireland

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
Fipronil
(S)-methoprene

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

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

Excipients (other ingredients): Butylhydroxyanisole (E320) 0.134mg,
Butylhydroxytoluene (E321) 0.067mg.

4. PHARMACEUTICAL FORM

Spot-on solution.

5. PACKAGE SIZE

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

6. INDICATION(S)

Flea, tick & Lice
treat & protect

Kills fleas, ticks, lice + flea eggs

Bob Martin Clear Plus 67 mg/ 60.3 mg Spot-on Solution for Small Dogs 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 8 weeks after application preventing re-infestation of the pet's home environment.

7. 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).

8. 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 packaging or you think that the medicine has not worked, please inform your veterinary surgeon

9. TARGET SPECIES

Small dogs 2-10kg and over 8 weeks old.

Example breeds small (adult) dogs 2-10kg: West Highland Terrier, Yorkshire terrier, Jack Russel, King Charles Spaniel.

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

To safeguard your health and that of your pet please read this carton carefully before you apply the product to your pet. The directions for use can be found under this flap on the back of the carton, and should be read before each use.

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

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:

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.

Avoid applying onto the fur and do not rub into the skin, as this will reduce the products 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.

Effective Flea Control

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.

The minimum interval between treatments is 4 weeks.

11. ADVICE ON CORRECT ADMINISTRATION

For external use only

12. WITHDRAWAL PERIOD

Not applicable

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in a dry place and in the original package

14. SPECIAL WARNING(S)<User Warnings>

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. Avoid contents coming into contact with your mouth, skin and eyes.

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 product is accidentally swallowed, or irritation of the eye persists, seek medical advice and show the packaging to the physician.

Do not smoke, drink or eat during application.

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

Treated animals should not be handled until the application site is dry; in particular, 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 during the early evening.

Recently treated animals should not be allowed to sleep with owners, especially children.

Wash hands thoroughly after use with soap and water.

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.

15. EXPIRY DATE

EXP End

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.

16. 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.

17. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

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

For animal treatment only.
[Distribution category]

AVM-GSL

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

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 61560/3011

21. MANUFACTURER’S BATCH NUMBER

Batch No:

22. OTHER INFORMATION

Bob Martin Clear is the registered trade mark of Pet Food Brands Limited

Gavin Hall
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