

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Flea Killing Mousse Plus for Cats and Kittens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Formulation:

<u>Active Ingredients</u>	<u>% w/w</u>
Pyrethrins (free)	0.05
Piperonyl Butoxide (free)	0.5
Sectrol Concentrate supplying:	
Pyrethrins (encapsulated)	0.1
Piperonyl Butoxide (encapsulated)	0.8

3. PHARMACEUTICAL FORM

Cutaneous foam

4. PACKAGE SIZE

5. TARGET SPECIES

Cats

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cutaneous use

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

AVM-GSL

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

The Bob Martin Company

Wemberham Lane

Yatton

Somerset BS49 4BS

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00715/4067

17. MANUFACTURER’S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Flea Killing Mousse Plus for Cats and Kittens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Formulation:

<u>Active Ingredients</u>	<u>% w/w</u>
Pyrethrins (free)	0.05
Piperonyl Butoxide (free)	0.5
Sectrol Concentrate supplying:	
Pyrethrins (encapsulated)	0.1
Piperonyl Butoxide (encapsulated)	0.8

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

150 g

4. ROUTE(S) OF ADMINISTRATION

Cutaneous use

5. WITHDRAWAL PERIOD

N/A

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

PACKAGE LEAFLET FOR:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Flea Killing Mousse Plus for Cats and Kittens

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

Formulation:

<u>Active Ingredients</u>	<u>% w/w</u>
Pyrethrins (free)	0.05
Piperonyl Butoxide (free)	0.5
Sectrol Concentrate supplying:	
Pyrethrins (encapsulated)	0.1
Piperonyl Butoxide (encapsulated)	0.8

4. INDICATION(S)

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cats

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

Cutaneous use

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

N/A

11. SPECIAL STORAGE PRECAUTIONS

[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

[It is recommended that the following reference to the VMD Website is included:]

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

<15. OTHER INFORMATION>

AVM - GSL

Vm 00715/4067

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

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

The Bob Martin Company

Wemberham Lane

Yatton

Somerset BS49 4BS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Flea Killing Mousse Plus for Cats and Kittens

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

Formulation:

<u>Active Ingredients</u>	<u>% w/w</u>
Pyrethrins (free)	0.05
Piperonyl Butoxide (free)	0.5
Sectrol Concentrate supplying:	
Pyrethrins (encapsulated)	0.1
Piperonyl Butoxide (encapsulated)	0.8

4. PHARMACEUTICAL FORM

Cutaneous foam

5. PACKAGE SIZE

6. INDICATION(S)

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

Cats

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

Cutaneous use

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

N/A

13. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

[Pharmaceuticals ONLY - The following statement should be included if there is an in-use shelf life (example: solution for injection)]

<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

14. SPECIAL WARNING(S) <User Warnings>

15. EXPIRY DATE

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

[It is mandatory for Exceptional Marketing Authorisations and recommended for others that the following reference to the VMD Website is included:]

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

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

[Distribution category]

AVM-GSL

For animal treatment only

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

Keep out of the sight and reach of children

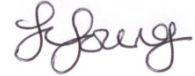
20. MARKETING AUTHORISATION NUMBER(S)

Vm 00715/4067

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION

Approved: 04/01/2018



No Approved Packaging