ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

NATURE/TYPE: Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Flea 57mg Tablets For Large Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Active Ingredient: 3 tablets each containing 57mg Nitenpyram.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

3 Tablets

5. TARGET SPECIES

Dogs over 11 kg

6. INDICATION(S)

Bob Martin Clear Flea 57mg Tablets are small, easy to use and a highly effective method of killing fleas. Used instead of a flea spray or shampoo the effects are almost immediate and will provide welcome relief from fleas within 24 hours.
Kills fleas fast. Starts killing fleas in 15 minutes. Kills 100% of fleas in 24 hours

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
The tablet can be given direct or hidden in some food and is suitable for pregnant and suckling mothers as well as puppies from 4 weeks.
Available in 2 pack sizes to suit your pet:

- Cats, Small Dogs and Puppies.
- Large Dogs over 11kg.

Product Performance

- Kills fleas fast.
- Starts killing fleas in 15 minutes.
- Kills 100% of fleas in 24 hours.

For Best Results

Weigh your dog to confirm the dose required.

11.1 - 57kg	1 tablet
Over 57kg	2 tablets

Give the tablets any day when fleas are detected. Repeat on any subsequent day but do not give more than one treatment per day.
Bob Martin Clear Flea 57mg Tablets should be used as part of an effective flea control programme. It is important to treat both your pet and its environment as fleas will also infect your pet's bedding, baskets and other resting areas. Use a product such as Bob Martin Clear Home Flea Spray to remove fleas from these areas.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: end {month/year}
Do not use these tablets after the expiry date.

11. SPECIAL STORAGE CONDITIONS

Keep blister in outer carton.
Do not store above 25°C.

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

Dispose of used packaging in household refuse.

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

For animal treatment only.

Legal Category AVM-GSL

UK Authorised Veterinary Medicinal Product

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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Distributed by: Pets Choice Ltd, Wemberham Lane, Yatton, North Somerset, BS49 4BS. UK. For further advice or information on the Bob Martin pet healthcare range of products please write to Freepost Bob Martin. Call our advice line on 00800 4378 7967. Email info@bobmartin.co.uk

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4059

17. MANUFACTURER'S BATCH NUMBER

Batch No: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE: PVC-aluminium blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Flea 57mg Tablets For Large Dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each tablet contains: Nitenpyram 57mg

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

11.4mg Nitenpyram

4. ROUTE(S) OF ADMINISTRATION

For oral use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

{number}

7. EXPIRY DATE

{month/year}
Do not use after expiry date

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bob Martin Clear Flea Tablets

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

Marketing authorisation holder:

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Batch release site and distributed by:

Pets Choice Ltd, Wemberham Lane, Yatton, North Somerset, BS49 4BS. UK.
Write to FREEPOST Bob Martin (no address required). Tel: 00800 4378 7967 . Email info@bobmartin.co.uk

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Flea 11.4mg Tablets for Cats, Small Dogs & Puppies
Bob Martin Clear Flea 57mg Tablets for Large Dogs

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

Each Tablet Contains:	Nitenpyram
For Cats, Small Dogs and Puppies	11.4mg
For Large Dogs	57mg

WHAT DO BOB MARTIN CLEAR FLEA TABLETS CONTAIN?
Each pack contains 3 tablets each containing the active ingredient Nitenpyram.

4. INDICATION(S)

WHAT ARE BOB MARTIN CLEAR FLEA TABLETS?
Bob Martin Clear Flea Tablets are small, easy to use and a highly effective method of killing fleas. Used instead of a flea spray or shampoo the effects are almost immediate and will provide welcome relief from fleas within 24 hours.

PRODUCT PERFORMANCE

- Kills fleas fast
- Starts killing fleas in 15 minutes
- Kills 100% of fleas in 24 hours

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

For the first hour after administration, the pet may scratch more than normal. This effect is caused by the fleas reacting to the product. In very rare cases this may present as transient signs of hyperactivity, panting, vocalization and excessive grooming/ licking.
Transient neurological signs such as muscle tremors, ataxia, and convulsions have also been reported in very rare occasions.
The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- Common (more than 1 but less than 10 animals in 100 animals)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals)
- Rare (more than 1 but less than 10 animals in 10,000 animals)
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

For animal treatment only.
Dogs and Cats

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

HOW SHOULD BOB MARTIN CLEAR FLEA TABLETS BE USED?
Weigh your cat / dog to confirm the dose required.

BOB MARTIN CLEAR FLEA 11.4 MG TABLETS FOR CATS, SMALL DOGS AND PUPPIES
1 – 11kg 1 tablet (11.4mg Nitenpyram)

BOB MARTIN CLEAR FLEA 57 MG TABLETS FOR LARGE DOGS
11.1 – 57kg 1 tablet (57mg Nitenpyram)
Over 57kg 2 tablets (57mg Nitenpyram)
Bob Martin Clear Flea Tablets can be given directly into the mouth or disguised in a little food.

9. ADVICE ON CORRECT ADMINISTRATION

HOW DO I USE THIS PRODUCT SAFELY?
Read the package leaflet before use.
WHEN SHOULD YOU USE BOB MARTIN CLEAR FLEA TABLETS?
Give the tablets any day when fleas are detected. Repeat on any subsequent day but do not give more than one treatment per day.

Fleas can be detected by parting the pet's coat to examine the skin or by combing its coat with a fine toothed flea comb. Frequent scratching or excessive grooming can also be signs of flea infestation.
Kills fleas fast

- Starts killing fleas in 15 minutes
- Kills 100% of fleas in 24 hours

Bob Martin Clear Flea Tablets are an effective method of killing adult fleas on your pet but can only be fully effective as part of a programme to eliminate fleas and larvae on the pet and in the pet's surroundings. Pet bedding and favourite resting areas should be vacuumed regularly and treated with a suitably approved insecticide preferably containing an Insect Growth Regulator (IGR). Consult your Veterinary Surgeon if signs of disease persist.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep blister in outer carton.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Do not use these tablets after the expiry date printed on the blister.

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

Dispose of used packaging in household refuse.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2021

15. OTHER INFORMATION>

Product Details
Bob Martin Clear Flea 11.4mg Tablets for Cats, Small Dogs & Puppies Vm 00879/4058
Bob Martin Clear Flea 57mg Tablets for Large Dogs Vm 00879/4059

Full range of pack sizes (3 and 6 tablets) - Not all pack sizes may be marketed.

AVM-GSL

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Approved: 13/05/21

D. Austin