ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON <THE IMMEDIATE PACKAGE>

Blister card/Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canac Dog Flea and Tick Collar, 15% w/w (Dimpylate)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

What's in this collar?
Each collar contains 15% w/w dimpylate (3.6 g dimpylate per collar)

3. PHARMACEUTICAL FORM

Collar

4. PACKAGE SIZE

1 collar

5. TARGET SPECIES

Dogs

6. INDICATION(S)

What does this collar do?
Canac Dog Flea and Tick Collar is a water-resistant collar that will kill fleas and ticks and prevent further re-infestation for up to 4 months. Flea kill begins almost immediately, but it may take several days for the active ingredient to spread throughout the entire coat.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Directions for use
Do not remove the collar from the pack until you are ready to fit it. Fasten the collar around the dog's neck, leaving enough room to insert two fingers between the collar and neck. Remember to loosen the collar as the dog grows bigger. Cut off excess collar extending beyond buckle and dispose of with the household refuse.

For external use only.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Is this collar suitable for my dog?
Do not use this collar if your dog is under 3 months old, is nursing puppies, or has been treated with other insecticides. Do not use any other insecticide within 7 days of removal of the collar. Remove the collar immediately should any signs of skin irritation, drowsiness, listlessness, tremor, hypersalivation or respiratory difficulties occur. These signs may develop soon after fixing of the collar. Fleas should be removed from young puppies and nursing females by careful use of a flea comb. If signs of disease persist or appear, consult your Veterinary Surgeon.

What precautions should I take myself?
Do not remove collar from pack until ready for use. Do not allow children to play with the collar. Do not allow children to suck or chew the collar. Do not smoke, eat or drink while handling collar. Do not sleep with pets wearing collars. Dimpylate/Diazinon is an organophosphate compound: DO NOT USE IF YOU ARE UNDER MEDICAL ADVICE TO AVOID ORGANOPHOSPHATES OR ANTICHOLINESTERASES. Avoid excessive handling of the collar. If you feel unwell after handling the collar, seek medical advice. Wash hands thoroughly with soap and water after handling the collar.

Are there any other precautions?
Do not allow animals to chew the collar. After fitting the collar, do not allow dogs to swim in ponds or other small bodies of water. This will not adversely affect the activity of the collar but poses a potential risk to aquatic life.

10. EXPIRY DATE

EXP end{month/year}

11. SPECIAL STORAGE CONDITIONS

Store the collar unopened. Protect from direct sunlight. Do not store above 25°C.

Do not remove the collar from the pack until you are ready to fit it.

After four months use, remove the collar and dispose of it with any remaining product/packaging in the household refuse.

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

This collar is EXTREMELY DANGEROUS to fish and aquatic life. Do not contaminate ponds, waterways or ditches with the collar or empty packaging.

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

Marketing Authorisation Holder:
Beaphar UK Limited
Rook Tree Farm
Withersfield Road, Great Wratting
Suffolk
CB9 7HD

Distributed by:
Beaphar UK Ltd
Rook Tree Farm
Withersfield Road
Great Wratting
Suffolk
CB9 7HD
UK

Manufacturer responsible for batch release:
Beaphar BV
Oude Linderteseweg 9
8102 EV Raalte
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 13907/3008

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Sachet}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canac Dog Flea and Tick Collar, 15% w/w (Dimpylate)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each collar contains 15% w/w dimpylate (3.6 g dimpylate per collar)

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

1 collar

4. ROUTE(S) OF ADMINISTRATION

For external use only.

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

Gavin Hall
Approved: 25 February 2025