

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

Johnson's Flea and Tick Collar for Dogs, 15% w/w

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

For dogs and puppies over six months old

6. INDICATION(S)

What does this collar do?

Johnson's Flea and Tick Collar for Dogs 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.

What size dog can this collar be used on?

The collar will fit most dogs. If fitted to a fully grown dog, allow enough space for 2 fingers to be inserted between the collar and neck. For a growing dog, remember to loosen the collar as the dog gets bigger.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

How do I fit the collar?

Simply slide the free end through the buckle, and tighten to give a comfortable fit. Cut off any excess collar with scissors, and dispose of safely.

What else can I do to prevent fleas?

Fleas spend three-quarters of their life cycle off your pet, in bedding, carpets, and soft furnishings. Treat these areas with a suitable household insecticide, and vacuum regularly.

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. If your dog develops any sign of skin irritation or signs of drowsiness, listlessness, or respiratory difficulties soon after fitting the collar, take it off immediately. 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

What should I do with the collar before and after use?

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

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

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

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 Limited
Rook Tree Farm
Withersfield Road
Great Wratting
Haverhill
Suffolk
CB9 7HD

Distributed by:

Johnson’s Veterinary Products Ltd.
5 Reddicap Trading Estate
Sutton Coldfield
West Midlands
B75 7DF
UK

Manufacturer responsible for batch release:

Beaphar BV
Oude Linderteseweg 9
8102 EV Raatle
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 05496/4030

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's Flea and Tick Collar for Dogs, 15% w/w

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.

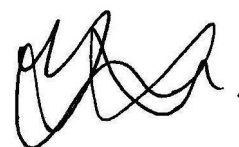
5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"



Approved: 22 April 2022