

**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 Tick and Flea Collar for Dogs, 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?

Johnson's Tick and Flea Collar for Dogs is a water-resistant collar that will kill ticks and fleas 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**

How do I fit the collar?

Slide the free end through the buckle and tighten to give enough room to insert two fingers between the collar and neck. Cut off excess collar extending beyond buckle and dispose of with the household refuse.

What size dog can this collar be used on?

The length of the collar is between 61.75 and 68.25 cm. For a growing dog, remember to loosen the collar as the dog gets bigger

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**

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 Raalte  
The Netherlands

**16. MARKETING AUTHORISATION NUMBER(S)**

Vm 05496/4032

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**18. ADDITIONAL INFORMATION**

What else can I do to prevent fleas?  
To help prevent reinfestation, animals’ bedding and regular resting areas, including carpets and soft furnishings, should be treated with a suitable insecticide and vacuumed regularly.

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

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Johnson's Tick and Flea Collar for Dogs, 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"**

Approved 25 April 2023

