

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 Collar for Cats, 15% w/w

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

What's in this collar?

Each collar contains 15% w/w dimpylate (2.1 g dimpylate per collar)

3. PHARMACEUTICAL FORM

Collar

4. PACKAGE SIZE

1 collar

5. TARGET SPECIES

Cats

For cats and kittens over 6 months old

6. INDICATION(S)

What does this collar do?

Johnson's Flea Collar for Cats is a water-resistant collar that will kill 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.

What size cat can this collar be used on?

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

How do I fit the collar?

The collar has been specifically designed to release your cat if it becomes caught up. To fit, simply slide the free end through the buckle, and tighten to leave enough room to insert two fingers between the collar and neck. Remember to loosen the collar if fitted onto a growing cat. Cut off any excess collar with scissors, wrap it in a bag and dispose of safely with your domestic rubbish. If your cat should become caught up, the special design will allow the collar to stretch, enabling your cat to slip its head out. 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 cat?

Do not use this collar if your cat is under 6 months old, is nursing kittens, or has been treated with other insecticides. Do not use any other insecticide within 7 days of removal of the collar. If your cat 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 kittens and nursing females by careful use of a flea comb. Do not allow animals to chew the collar. 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.

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.

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 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 05496/4029

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 Collar for Cats, 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.

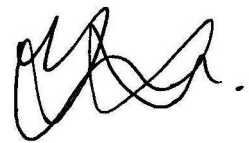
5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"



Approved: 21 April 2022