

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield 0.77 g medicated collar for small and medium sized dogs
Deltamethrin

2. STATEMENT OF ACTIVE SUBSTANCES

Each 19 g collar contains:
Deltamethrin 0.77 g

3. PHARMACEUTICAL FORM

Medicated collar

4. PACKAGE SIZE

1 collar
2 collars

5. TARGET SPECIES

Dogs

6. INDICATION(S)

The veterinary medicinal product provides:

- Persistent flea (*Ctenocephalides felis*) killing activity for 16 weeks;
- Persistent tick (*Ixodes ricinus*) killing activity for 6 months;
- Sandfly (*Phlebotomus perniciosus*) anti-feeding and killing activity for 5.5 months.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external, cutaneous use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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9. SPECIAL WARNING(S), IF NECESSARY

Keep in the original packaging until use in order to prevent children from getting access to the product.

Dogs wearing the collar should not be allowed to sleep in the same bed as their owners, especially children.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the sachet: use immediately.

11. SPECIAL STORAGE CONDITIONS

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

Read the package leaflet before use.

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

Beaphar B.V.
Drostenkamp 3
8101 BX Raalte
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41941/3001

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield collar

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Deltamethrin 0.77 g

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

1 x 48 cm

4. ROUTE(S) OF ADMINISTRATION



cutaneous use

5. WITHDRAWAL PERIOD(S)

-

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}



[optional Beaphar logo]

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Canishield 0.77 g medicated collar for small and medium sized dogs

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

Marketing authorisation holder:

Beaphar B.V.
Drostenkamp 3
8101 BX Raalte
The Netherlands

Manufacturer responsible for batch release:

Beaphar B.V.
Oude Linderteseweg 9
8102 EV Raalte
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield 0.77 g medicated collar for small and medium sized dogs
Deltamethrin

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

One black medicated collar, which releases a white powder. This 48 cm collar (19 g) contains:

Active substance:

Deltamethrin 0.77 g

4. INDICATION(S)

The veterinary medicinal product provides:

- Persistent flea (*Ctenocephalides felis*) killing activity for 16 weeks;
- Persistent tick (*Ixodes ricinus*) killing activity for 6 months;
- Sandfly (*Phlebotomus perniciosus*) anti-feeding and killing activity for 5.5 months.

5. CONTRAINDICATIONS

Do not use in puppies less than 7 weeks of age.
Do not use on dogs with skin lesions.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use on cats. Deltamethrin is harmful to cats.

6. ADVERSE REACTIONS

In rare cases, local skin reactions (itching, redness, hair loss) involving the neck or the skin in general have been observed. Altered behaviour (e.g. lethargy or hyperactivity) often associated with skin irritation has been reported in very rare cases, too.

On very rare occasions, gastrointestinal symptoms such as vomiting, diarrhoea and hypersalivation have been observed.

In very rare cases, neuromuscular problems such as uncoordinated movements and muscle tremors have been observed. The symptoms usually subside within 48 hours after removal of the collar.

If any of these symptoms occur, the collar should be removed and contact with a veterinarian is advised.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinarian.

7. TARGET SPECIES

Dogs

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

For external, cutaneous use only. One collar per dog is to be fastened around the neck.

9. ADVICE ON CORRECT ADMINISTRATION



Remove the collar from the protective sachet right before use. Fit the collar around the animal's neck neither too loose nor too tight: two fingers side-by-side should fit

between the collar and the dog's neck. Cut off any excess length extending beyond 5 cm. Check periodically and adjust the fit easily by applying pressure on top of the buckle and then sliding the collar into the correct position.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the sachet: use immediately.
Keep the sachets in the outer carton.

12. SPECIAL WARNING(S)

Special warnings for each target species:

As the collar exerts its full effect after one week, the collar should preferably be applied 1 week before animals are likely to become exposed to infestation.

Ticks and sandflies will be killed and fall off the host within 48 and 24 hours after exposure respectively without having had a blood meal, as a rule. An attachment of single ticks or bite of single sandflies after treatment cannot be excluded. For this reason, a transmission of infectious diseases by ticks or sandflies cannot be completely excluded if conditions are unfavourable.

For optimal control of flea infestations in multi-pet households, all dogs in the household should be treated at the same time.

Fleas from pets often infest the animal's basket, bedding and regular resting areas, such as carpets and soft furnishings. These should be treated in cases of massive infestation and upon the initiation of control measures with a suitable insecticide, and vacuumed regularly.

Special precautions for use in animals:

In case of skin lesions, remove the collar until symptoms have resolved.
The influence of shampooing on the duration of efficacy has not been investigated.
Occasional contact with water does not reduce the effectiveness of the collar.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental ingestion of this product may cause adverse reactions, including neurotoxic effects.

Keep the product in the original carton. Keep the collar in the sachet until use. Do not smoke, eat or drink while handling the collar. Do not allow children to play with the collar or to put it into their mouths. Immediately dispose of any remnants or cut-offs of the collar. Wash hands with cold water after fitting the collar.

Avoid prolonged contact with the collar or dog wearing the collar. This includes sharing a bed with dogs wearing the collar; this is particularly important for children. In case of accidental oral exposure or ingestion, seek medical advice and show the package leaflet or the label to the doctor.

Deltamethrin may cause hypersensitivity (allergic) reactions in sensitive people. People with known hypersensitivity to deltamethrin should avoid contact with the veterinary medicinal product and the treated animal. Seek medical advice in case of hypersensitivity reactions.

Other precautions

Deltamethrin is toxic for aquatic organisms. Dogs wearing the collar are not allowed to enter watercourses.

Use during pregnancy, lactation or lay

Laboratory studies have not produced any evidence of developmental or embryotoxic effect. However, the safety of the veterinary medicinal product has not been established in pregnant dogs. Therefore, the product should be used during pregnancy and lactation only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not use with other ectoparasiticides containing organophosphates.

Overdose (symptoms, emergency procedures, antidotes):

In the unlikely event of the dog eating the collar, the following symptoms may occur: Uncoordinated movements, tremor, drooling of saliva, vomiting, rigidity of the hindquarters. These symptoms usually subside within 48 hours. For more information concerning symptomatic treatment it is advised to contact your local veterinarian.

Incompatibilities:

Not applicable.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

The product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:

Cardboard box containing 1 or 2 collars.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

United Kingdom:

Beaphar UK Ltd,

Rook Tree Farm

Withersfield Road

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Suffolk CB9 7HD

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