

PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield 1.04 g medicated collar for large sized dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 26 g collar contains:

Deltamethrin 1.04 g

3. PACKAGE SIZE

1 collar

2 collars

4. TARGET SPECIES

Dogs

5. 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.

6. ROUTES OF ADMINISTRATION

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

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the sachet: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Keep the sachet(s) in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Beaphar B.V.
Drostenkamp 3
8101 BX Raalte
Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 41941/5000

15. BATCH NUMBER

Batch {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

[Front of outer package]

Do not use on cats. Deltamethrin is harmful to cats.



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

Deltamethrin is continuously released from the collar to the skin and fur whilst the collar is being worn.

Accidental ingestion of this product may cause adverse reactions, including neurological 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

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

Read the package leaflet before use.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

AVM-GSL

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield collar



2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

DELTAMETHRIN 1.04 G

3. BATCH NUMBER

Batch {number}

4. EXPIRY DATE

EXP {month/year}

[optional Beaphar logo]



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

1 x 65 cm

WITHDRAWAL PERIOD

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield 1.04 g medicated collar for large sized dogs

2. COMPOSITION

One 65 cm collar (26 g) contains:

Active substance:

Deltamethrin 1.04 g

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

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

6. 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.

Do not let the dog chew on or ingest the collar.

Special precautions for use in animals:

In case of skin damage (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:

Deltamethrin is continuously released from the collar to the skin and fur whilst the collar is being worn.

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

Special precautions for the protection of the environment

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 parasitic treatments containing organophosphates or pyrethroids.

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.

Special precautions for the protection of the environment:

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

7. ADVERSE EVENTS

Rare (1 to 10 animals / 10,000 animals treated):	Application site reactions (pruritis, erythema, hair loss) ¹
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Behavioural disorder (lethargy, hyperactivity) ² Digestive tract disorders (vomiting, diarrhoea, hypersalivation) Neuromuscular disorder (ataxia, muscle tremor) ³

¹ Involving the neck or the skin in general

² associated with skin irritation

³ 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.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {<https://www.gov.uk/report-veterinary-medicine-problem>}.

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 temperature 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 PRECAUTIONS FOR DISPOSAL

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

Medicines should not be disposed of via wastewater.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes:

Cardboard box containing 1 or 2 child resistant sachets.
Not all pack sizes may be marketed.

Vm 41941/5000

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

May 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.>

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:

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

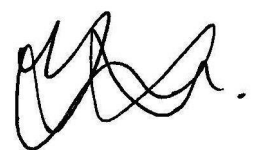
Local representatives and contact details to report suspected adverse reactions:

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
Great Wratting
Suffolk CB9 7HD
T: +44 (0)333 0066236
E: info@uk.beaphar.com

17. OTHER INFORMATION



Approved: 15 May 2023