ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield 1.04 g medicated collar

2. STATEMENT OF ACTIVE SUBSTANCES

Each 65 cm collar (26 g) contains:
Deltamethrin …….. 1.04 g

3. PACKAGE SIZE

1 collar
2 collars

4. TARGET SPECIES

Large sized dogs

5. INDICATIONS

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 cutaneous use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special temperature storage conditions.
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 OF THE MARKETING AUTHORISATION HOLDER

beaphar

14. MARKETING AUTHORISATION NUMBERS

Vm 41941/3000

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield collar

1 x 65cm

Optional logo

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Deltamethrin 1.04 g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Canishield 1.04 g medicated collar for large sized dogs

2. Composition

Each 65 cm collar (26 g) contains:
Active substance : Deltamethrin 1.04 g
One black medicated collar, which releases a white powder.

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

6. Special warnings

Special warnings:
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.

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.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual dog.

Resistance to pyrethroids and in particular to deltamethrin has been reported in fleas (*C. felis*) and ticks (*Rhipicephalus sanguineus*) in dogs. The use of this product should take into account local information about susceptibility of the target parasites, where available."

Special precautions for safe use in the target species:
In case of skin lesions, remove the collar until symptoms have resolved.

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.

Special precautions for the protection of the environment:
Deltamethrin is toxic for aquatic organisms. Dogs wearing the collar are not allowed to enter watercourses.

Pregnancy and lactation:
Laboratory studies have not produced any evidence of developmental or embryotoxic effects. However, the safety of the veterinary medicinal product has not been established in pregnant dogs. Use 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:
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.

Major incompatibilities:
Not applicable.

7. Adverse events

Dogs

Rare (1 to 10 animals / 10,000 animals treated):	Localised skin reactions (pruritus, erythema, hair loss) [1],
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Altered behaviour (lethargy, hyperactivity)[2], Digestive tract disorders (vomiting, diarrhoea, hypersalivation), Neuromuscular disorders (such as ataxia, muscle tremor)[3]

[1]involving the neck or skin in general
[2] often 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 marketing authorisation holder or the local representative of the marketing authorisation holder, using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

For 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 periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the sachet(s) in the outer carton.
Shelf life after first opening of the immediate packaging: use immediately.

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.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription:
BE, BG, HR, CY, CZ, EE, ES, FR, EL, HU, IT, LV, LT, NL, NO, MT, PL, PT, SI, SK, RO, UK(NI).

Veterinary medicinal product subject to prescription:
IE, DE

14. Marketing authorisation numbers and pack sizes

Vm 41941/3000
Pack sizes:
Cardboard box containing 1 or 2 child resistant sachets
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

December 2022

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)..

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release

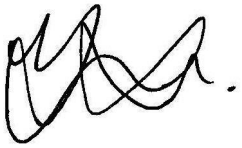
Marketing authorisation holder:	Manufacturer responsible for batch release:
Beaphar B.V. Drostenkamp 3 8101 BX Raalte The Netherlands	Beaphar B.V Oude Linderteseweg 9 8102 EV Raalte The Netherlands

Marketing authorisation holder and contact details to report suspected adverse reactions:

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.

17. Other information



Approved: 15 May 2023