Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Canishield 0.77 g medicated collar for small and medium sized dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One 48 cm collar (19 g) contains:

Active substance:
Deltamethrin 0.77 g

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated collar.
Black collar, which releases a white powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs

4.2 Indications for use, specifying the target species

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

4.3 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.

4.4 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.

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

In rare cases, local skin reactions (pruritus, erythema, 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.
In very rare occasions, gastrointestinal symptoms such as vomiting, diarrhoea and hypersalivation have been observed.
In very rare cases, neuromuscular problems such as ataxia and muscle tremor 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) during the course of one treatment)
- 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).

4.7 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.

4.8 Interaction with other medicinal products and other forms of interactions

Do not use with other ectoparasiticides (pyrethroids, organophosphates).

4.9 Amounts to be administered and administration route

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticides, insecticides and repellents, pyrethrins and pyrethroids
ATCvet code: QP53AC11.

5.1 Pharmacodynamic properties

Insects and acarines are exposed to deltamethrin through contact. The mechanism of action is based on a sustained increase in the sodium permeability of the insect's nerve membranes. This results in hyperactivity followed by paralysis (shock effect), tremor and death of the parasite.

5.2 Pharmacokinetic particulars

Deltamethrin is slowly and continuously released from the collar into the dogs' coat. The active substance spreads from the site of direct contact over the entire skin surface through the lipids and in the hair.
Deltamethrin is not absorbed systemically by the host.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbon black
Epoxidized soybean oil
Diisnonyl adipate
Triphenyl phosphate
Polyvinyl chloride
Calcium stearate
Zinc stearate
Stearic acid

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the sachet: use immediately.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the sachets in the outer carton.

6.5 Nature and composition of immediate packaging

Material of the primary packaging:
PET/PE/aluminium/surlyn sachet containing one collar.

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with national requirements.
This product should not enter water courses as this may be dangerous for fish and other aquatic organisms.

7 MARKETING AUTHORISATION HOLDER

Beaphar B.V.
Drostenkamp 3
PO Box 7
8100 AA Raalte
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA10455/003/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd November 2019

10 DATE OF REVISION OF THE TEXT