

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

PREVENDOG 1.304 g medicated collar for large to very large dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One collar of 75 cm (32.60g) contains:

Active substance(s):

Deltamethrin	1.304 g
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Excipient(s):

Titanium dioxide (E171)	0.465 g
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Charcoal, activated	0.024 g
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For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated collar

Grey collar

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs (> 25 kg) for large to very large dogs

4.2 Indications for use, specifying the target species

Deltamethrin-sensitive parasite infestations.

Prevention of tick re-infestation (*Ixodes ricinus* and *Rhipicephalus sanguineus*) through an acaricidal effect for 6 months.

Prevention of sandfly bites (*Phlebotomus perniciosus*) due to repellent (anti-feeding) effect for 5 months.

Prevention of mosquito bites (*Culex pipiens*) due to repellent (anti-feeding) effect for 6 months.

4.3 Contraindications

In the absence of studies, do not use in puppies less than 7 weeks of age.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in cats.

Do not use on dogs with skin lesions.

4.4 Special warnings for each target species

As the collar exerts its full effect after one week, the collar should be preferably applied 1 week before animals are likely to become exposed to infestation. Ticks would be killed and fall off the host within 24 to 48 hours after infestation without having had a blood meal, but an attachment of single ticks after treatment cannot be excluded. Thus, a transmission of infectious diseases by ticks cannot be excluded. Under unfavourable conditions the transmission of infectious diseases through sandflies can not be ruled out entirely.

4.5 Special precautions for use

Special precautions for use in animals

The effect of shampooing on the efficacy of the product has not been tested.

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

Accidental ingestion of this product may cause adverse effects, 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. Keep away from food, drink and animal feeding stuffs.

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.

In case of accidental oral exposure or ingestion seek medical advice and show the package leaflet or the label to the doctor.

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.

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

While occasional contact with water does not reduce the effectiveness of the collar, Deltamethrin is toxic for the fish and other aquatic organisms. Dogs wearing the collar should not be allowed to swim in the water courses.

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 which might indicate a local or general hypersensitivity reaction.

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. Treatment should be symptomatic as no specific antidote is known.

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).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects. The safety of the veterinary medicinal product has not been established during pregnancy. The use is not recommended during pregnancy. Can be used during lactation.

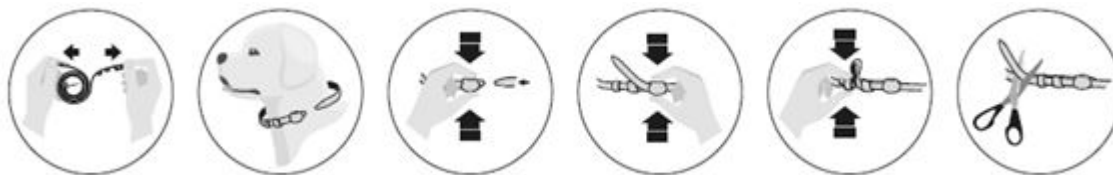
4.8 Interaction with other medicinal products and other forms of interactions

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

4.9 Amounts to be administered and administration route

One collar per dog. The 75 cm long collar is to be used on large to very large dogs. Fits necks up 65 cm.

Remove the collar from its packaging and separate the peel-away comfort strip. Adjust the collar around the animal's neck without tightening it too tight. Two fingers side-by-side should fit between the band and the dog's neck. Slide the end through the buckle and cut off any excess length extending beyond 5 cm.



This collar is designed with a safety-closure mechanism (anti-strangulation safety). In the unlikely event of a dog being trapped, the dog's own strength is sufficient to widen the collar to allow for quick release.

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

In case of accidental ingestion of the collar by the dog, contact your veterinary surgeon. The following symptoms of intoxication may be observed: uncoordinated movements, tremor, hypersalivation, vomiting, rigidity of the hindquarters. These symptoms usually subside within 48 hours. In case of accidental ingestion the animal owner should contact the veterinary surgeon and should not initiate symptomatic treatment, the veterinary surgeon should assess the need for any symptomatic treatment.

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

Deltamethrin, a molecule of the synthetic pyrethroid family, is characterized by its acarid and insecticidal activity. Acting by modifying the permeability of sodium channels, the molecule causes hyperexcitation, followed by paralysis (shock effect), tremors and parasite mortality.

Deltamethrin has a repellent effect against phlebotomes, vectors of *Leishmania infantum* (protozoan, agent of leishmaniasis).

5.2 Pharmacokinetic particulars

Deltamethrin is continuously released from the collar into the coat and the fatty film covering the skin. The active substance spreads from the site of direct contact over the skin surface through the lipids and in the hair.

Dermal absorption of deltamethrin is low.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyvinyl chloride
Calcium stearate
Soybean oil, epoxidized
Diisooctyl adipate
Titanium dioxide (E171)
Triphenyl phosphate
Charcoal, activated
Calcium zinc stearates

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 immediate packaging: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Each collar is packaged in a sealed sachet made polyethylene terephthalate-aluminium-polypropylene.

Pack sizes:

Cardboard or in a metallic box with one sachet containing 1 collar of 75 cm.

Cardboard or in a metallic box with two sachets containing 1 collar of 75 cm.

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

7 MARKETING AUTHORISATION HOLDER

Vetpharma Animal Health, S.L.
Les Corts, 23
08028 Barcelona
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10516/021/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th January 2019

10 DATE OF REVISION OF THE TEXT