

[Version 8.1,01/2017]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DELTATIC medicated collar for very small dogs [IT, PT, CY, RO, BG, SI]

FRONTAL DELTA medicated collar for very small dogs [ES]

SERATIC medicated collar for very small dogs [BE, EL]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One collar of 35 cm (15.90 g) contains:

Active substance:

Deltamethrin 0.636 g

Excipient:

Titanium dioxide (E171) 0.239 g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Medicated collar

White collar

4. CLINICAL PARTICULARS

4.1 Target species

Dogs (0 – 5 kg) for very small dogs

4.2 Indications for use, specifying the target species

The collar demonstrates:

- Repellent effect (anti-feeding) during 5 months for sandflies (*Phlebotomus perniciosus*)
- Repellent effect for 6 months for culicid mosquitoes (*Culex pipiens*)

The collar prevents from:

- Tick infestation for 6 months.
- Fleas infestation for 4 months.

It has been proved the repellent efficacy (antifeeding) against *Phlebotomus spp*, so it can be considered as part of the program of prevention for Leishmaniasis and the culex mosquitoes of the complex *Culex pipiens*..

4.3 Contraindications

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

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

Do not use in cats.

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 cannot 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 sachet with the collar in the outer carton until ready to use.

Avoid letting children touch the collar, play with it or put it into their mouth. Immediately dispose of any remnants or cut-offs of the collar. Wash hands with cold water after fitting the collar.

Avoid prolonged intensive contact with the collar or an animal wearing a collar (e.g. sleeping with), particularly children

Do not smoke, eat or drink while handling the collar. Keep away from food, drink and animal feeding stuffs.

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

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. Remove the collar before allowing the dog to swim and before bathing the dog to avoid adverse effects on aquatic organisms. Dogs must be prevented from swimming in water for the first five days of wearing the collar.

4.6 Adverse reactions (frequency and seriousness)

In rare occasions, it has been observed:

- local allergic 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.
- gastrointestinal symptoms such as vomiting, diarrhoea and hypersalivation.
- neuromuscular problems such as ataxia and muscular tremor.

Moreover, in rare occasions it also has been notified an altered behaviour (for example, lethargy and hyperactivity), sometimes associated with the skin irritation.

In general, the symptoms disappear within 48 hours after the collar has been 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

It has not been observed secondary effects in pregnant bitches using the collar during the pregnancy and lactation period, neither in puppies of mothers treated with the collar until the weaning.

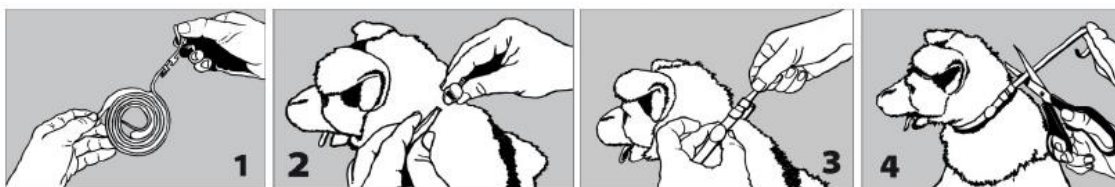
4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

External use. 1 collar/animal. The 35-cm long collar is to be used on very small dogs. Fits necks up to 28 cm (35 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 clinical signs of intoxication may be observed: uncoordinated movements, tremor, hypersalivation, vomiting, rigidity of the hindquarters. These clinical signs 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

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

Deltamethrin, the pharmacologically active substance of the collar, is a molecule of the synthetic pyrethroid family (Type-II), is characterized by its acarid and insecticidal activity. Acting in invertebrates 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
Calcium zinc stearates

6.2 Major incompatibilities

Not applicable

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 48 months
Shelf-life after first opening the immediate packaging: use immediately.

6.4. Special precautions for storage

Keep the sachets in the outer carton / metallic box in order to protect from light.

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 35 cm.
Cardboard or in a metallic box with two sachets containing 1 collar of 35 cm.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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.

Deltamethrin is toxic for bees, fish and other aquatic organisms. This product should not enter water courses. Do not throw the collar to the environment or water after using it.

7. MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L.
Les Corts, 23
08028 - Barcelona
Spain

8. MARKETING AUTHORISATION NUMBERS

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable