

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard / Metallic Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

FRONTAL DELTA medicated collar for large to very large dogs [ES]

SERATIC medicated collar for large to very large dogs [BE, EL]

Deltamethrin

2. STATEMENT OF ACTIVE SUBSTANCES

One collar of 75 cm (32.60g) contains:

Active substance:

Deltamethrin 1.304 g

3. PHARMACEUTICAL FORM

Medicated collar

4. PACKAGE SIZE

1 x 75 cm, 2 x 75 cm

5. TARGET SPECIES

Dogs

6. INDICATIONS

The collar demonstrates:

- Repellent effect (anti-feeding) during 5 months for sandflies (*Phlebotomus perniciosus*)
- Repellent effect for 6 months for culicids 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*.

7. METHOD AND ROUTES OF ADMINISTRATION

Fits necks up to 65 cm.

Anti-strangulation safety

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

Keep in the original packaging until use in order to prevent children from getting access to the product.

Dogs wearing the collar should not be allowed to sleep in the same bed as their owners, especially children.

10. EXPIRY DATE

EXP {month/year}

Once opened use immediately.

11. SPECIAL STORAGE CONDITIONS

Keep the sachets in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VETPHARMA ANIMAL HEALTH, S.L.

Les Corts, 23

08028 - Barcelona

Spain

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

<Batch><Lot> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DELTATIC /FRONTAL DELTA /SERATIC

Deltamethrin



2. NAME OF THE MARKETING AUTHORISATION HOLDER



3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

DELTATIC medicated collar for large to very large dogs [IT, PT, CY, RO, BG, SI]
FRONTAL DELTA medicated collar for large to very large dogs [ES]
SERATIC medicated collar for large to very large dogs [BE, EL]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

AB7 SANTE
Chemin des Monges
31450 Deyme
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

DELTATIC medicated collar for large to very large dogs [IT, PT, CY, RO, BG, SI]
FRONTAL DELTA medicated collar for large to very large dogs [ES]
SERATIC medicated collar for large to very large dogs [BE, EL]

Deltamethrin

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

One collar of 75 cm (32.60g) contains:

Active substance:

Deltamethrin 1.304 g

Excipient:

Titanium dioxide (E171) 0.489 g

White medicated collar

4. INDICATIONS

The collar demonstrates:

- Repellent effect (anti-feeding) during 5 months for sandflies (*Phlebotomus perniciosus*)
- Repellent effect for 6 months for culicids 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*.

5. CONTRAINDICATIONS

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 in dogs with skin lesions.

6. ADVERSE REACTIONS

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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

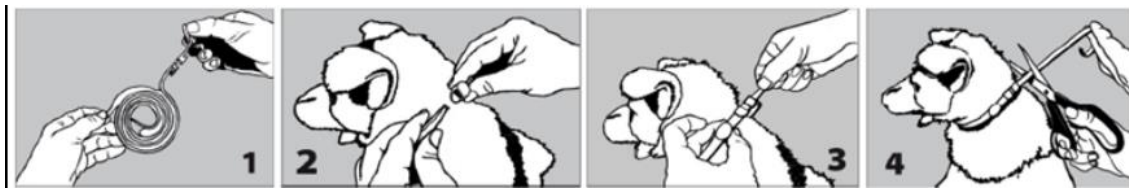
Dogs (> 25 kg) for large to very large dogs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

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 dogs own strength is sufficient to widen the collar to allow for quick release.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

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.

Pregnancy and lactation:

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.

Interaction with other medicinal products and other forms of interaction:

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

Overdose (symptoms, emergency procedures, antidotes):

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.

Incompatibilities:

Not applicable

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.