

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE {NATURE/TYPE}**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Seresto Flea and Tick Control 4.50 g + 2.03 g, Collar for Large Dogs > 8 kg.

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each collar contains: 4.50 g Imidacloprid, 2.03 g Flumethrin

Grey, odour free collar.

### **3. PACKAGE SIZE**

1 x 70 cm collar

### **4. TARGET SPECIES**

Dogs

### **5. INDICATIONS**

Kills ticks, fleas and lice and repels ticks (“anti-feeding”). Indirect protection against transmission of canine babesiosis and canine ehrlichiosis. 7 - 8 months protection. Water resistant veterinary medicinal product.



Tick



Flea



Larvae



Louse

### **6. ROUTES OF ADMINISTRATION**

Cutaneous use.

### **7. WITHDRAWAL PERIODS**

### **8. EXPIRY DATE**

Exp. {mm/yyyy}

### **9. SPECIAL STORAGE PRECAUTIONS**

Keep the bag with the collar in the outer box until use.

### **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**

Elanco GmbH

**14. MARKETING AUTHORISATION NUMBER**

Vm 52127/5107 (GB)

Vm 52127/3042 (NI)

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bag}**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Seresto Flea and Tick Control 4.50 g + 2.03 g, Collar

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each collar contains: 4.5 g Imidacloprid, 2.03 g Flumethrin

**3. TARGET SPECIES**

Dogs (> 8 kg).

**4. ROUTES OF ADMINISTRATION**

Read the package leaflet before use.

Cutaneous use.

**5. WITHDRAWAL PERIODS**

**6. EXPIRY DATE**

Exp. {mm/yyyy}

**7. SPECIAL STORAGE PRECAUTIONS**

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Elanco GmbH

**9. BATCH NUMBER**

Lot {number}

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

Seresto Flea and Tick Control 4.50 g + 2.03 g, Collar for Large Dogs >8 kg

#### **2. Composition**

Each grey, odour free collar of 70 cm (45 g) contains 4.5 g imidacloprid and 2.03 g flumethrin as active substances and is embossed with the veterinary medicinal product name on one side.

#### **3. Target species**

Dogs

#### **4. Indications for use**

For the treatment and prevention of flea (*Ctenocephalides felis*, *C. canis*) infestation for 7 to 8 months. Protects the animal's immediate surroundings against flea larvae development for 8 months.

This veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinary surgeon.

The veterinary medicinal product has persistent acaricidal (killing) efficacy against tick infestations (*Ixodes ricinus*, *Rhipicephalus sanguineus*, *Dermacentor reticulatus*) and repellent (anti-feeding) efficacy against tick infestations (*Ixodes ricinus*, *Rhipicephalus sanguineus*) for 8 months. It is effective against larvae, nymphs and adult ticks.

Ticks already on the dog prior to treatment may not be killed within 48 hours after collar application and may remain attached and visible. Therefore removal of ticks already on the dog at the time of application is recommended. If you are unsure how to safely remove ticks from your animal, seek professional guidance. The prevention of infestations with new ticks starts within two days after application of the collar.

For treatment of biting/chewing lice (*Trichodectes canis*) infestation.

The veterinary medicinal product provides indirect protection against transmission of the pathogens *Babesia canis vogeli* and *Ehrlichia canis* from the tick vector *Rhipicephalus sanguineus*, thereby reducing the risk of canine babesiosis and canine ehrlichiosis for 7 months.

## **5. Contraindications**

Do not treat puppies less than 7 weeks of age.

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

## **6. Special warnings**

### Special warnings:

Ticks will be killed and fall off the host within 24 to 48 hours after infestation without having had a blood meal, as a rule. An attachment of single ticks after treatment cannot be excluded. For this reason, a transmission of infectious diseases by ticks cannot be completely excluded if conditions are unfavourable.

Ideally, the collar should be applied before the beginning of the flea or tick season.

As with all long-term topical veterinary medicinal products, periods of excessive seasonal hair shedding may lead to transient slight reduction of efficacy by loss of hair-bound portions of the active ingredients. Replenishment from the collar starts immediately so that full efficacy will be re-established without any additional treatment or collar replacement.

For optimum control of flea problems in heavily infested households it may be necessary to treat the environment with a suitable insecticide.

The veterinary medicinal product is water resistant; it remains effective if the animal becomes wet. However, prolonged, intense exposure to water or extensive shampooing should be avoided as the duration of activity may be reduced. Studies show that monthly shampooing or water immersion does not significantly shorten the 8 months efficacy duration for ticks after redistribution of the active substances in the coat whereas the veterinary medicinal product's flea efficacy gradually decreased, starting in the 5th month.

### Special precautions for safe use in the target species:

Do not allow animals to chew the collar.

Ensure that the collar is fitted correctly (see section "advice on correct administration")

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

The product may cause hypersensitivity (allergic) reactions in some people. People with known hypersensitivity to imidacloprid or flumethrin should avoid contact with the product.

Numbness, headache and dizziness have been reported after user contact with the collar or with treated animals. Skin, eye, and respiratory tract irritation have been reported in very rare cases.

Do not allow children to play with the collar, particularly sucking it or putting it into their mouths.

Do not sleep with pets wearing collars, especially children. Imidacloprid and flumethrin are continuously released from the collar to the skin and fur whilst the collar is being worn.

In case of eye contact, flush eyes thoroughly with cold water. In case of skin contact, wash the skin with soap and cold water.

If you develop any of these symptoms, or they persist over time, seek medical advice and show the package leaflet or the label to the physician.

Keep the bag with the collar in the outer packaging until use.

Immediately dispose of any remnants or off-cuts of the collar (see section “advice on correct administration”).

Wash hands with cold water after fitting the collar.

Special precautions for the protection of the environment:

See section, “Special Precautions for Disposal”.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established in target animals during pregnancy and lactation. The use is not recommended during pregnancy and lactation.

Laboratory studies with either flumethrin or imidacloprid in rats and rabbits showed no teratogenic, or foetotoxic effects.

Fertility:

Laboratory studies with either flumethrin or imidacloprid in rats and rabbits have not produced any effects on fertility or reproduction

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

Due to the nature of the collar overdosage is unlikely and signs of overdosage are not to be expected.

An overdosage of 5 collars around the neck was investigated in adult dogs for an 8 month period and in 7 week old puppies for a 6 month period and no adverse effects were observed besides slight hair loss and mild skin reactions.

In the unlikely event of the animal eating the collar mild gastrointestinal symptoms (e.g. loose stool) may occur.

Major incompatibilities:

None known.

## 7. Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Application site disorders <sup>1</sup> (e.g. Erythema, Hair loss, Pruritus) Behavioural disorder <sup>2</sup> (e.g. Scratching) Diarrhoea <sup>3</sup> , Hypersalivation <sup>3</sup> , Vomiting <sup>3</sup> Ataxia <sup>4</sup> , Convulsion <sup>4</sup> , Tremor <sup>4</sup> Appetite disorder <sup>3</sup> , Depression <sup>3</sup>
Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Application site disorders <sup>4</sup> (e.g. Dermatitis, Eczema, Inflammation, Lesion) Hypersensitivity reaction (e.g. Contact dermatitis) Anorexia, Lethargy

<sup>1</sup> Signs usually resolve within 1 to 2 weeks. In single cases, temporary collar removal is recommended until signs resolve.

<sup>2</sup> May be observed in animals that are not used to wearing collars on the first few days after fitting. Ensure that collar is fitted correctly.

<sup>3</sup> Slight and transient reactions that might occur with initial use.

<sup>4</sup> In these cases, collar removal is recommended.

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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

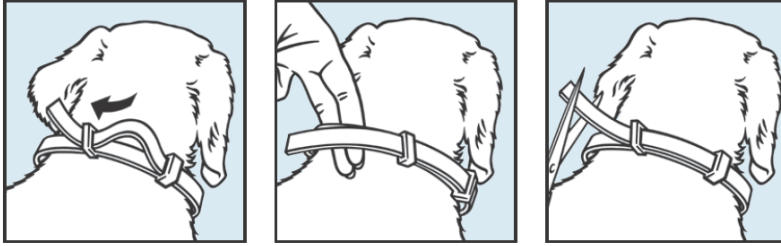
## 8. Dosage for each species, routes and method of administration

Cutaneous use. Dogs above 8 kg receive one collar of 70 cm length.

One collar per animal to be fastened around the neck. For external use only.

## 9. Advice on correct administration

Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar. Adjust the collar around the animal's neck without tightening it too tight (as a guide, it should be possible to insert 2 fingers between the collar and the neck). Pull excess collar through the loop and cut off any excess length extending beyond 2 cm.



The collar should be worn continuously for the 8 month protection period and should be removed after the treatment period. Check periodically and adjust fit if necessary, especially when puppies are rapidly growing.

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

Keep the bag with the collar in the outer box until use. Do not use after expiry date stated on the bag and outer box. The expiry date refers to the last day of that month.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

The veterinary medicinal product should not enter water courses as imidacloprid and flumethrin 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.

#### **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 52127/5107 (GB)

Vm 52127/3042 (NI)

Pack size: one collar

## **15. PID LINK (Do not print heading)**

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## **16. Contact details**

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

Elanco GmbH  
Heinz-Lohmann Strasse 4  
Groden  
27472 Cuxhaven  
Germany

GB: PV.GBR@elancoah.com  
Tel: +44 3308221732

NI: PV.XXI@elancoah.com  
Tel: +44 3308221732

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH  
Projensdorfer Str. 324, 24106 Kiel  
Germany

## **17. Other information**

Both active ingredients are slowly and continuously released in low concentrations from the polymer matrix system of the collar towards the animal. Both actives are present in the dog's haircoat in acaricidal/insecticidal concentrations during the entire efficacy period. The active substances spread from the site of direct contact over the entire skin surface. Target animal overdose and serum kinetic studies have established that imidacloprid reached the systemic circulation transiently while flumethrin was mostly not measurable. Oral absorption of both active substances is not relevant for the clinical efficacy.

Efficacy against fleas (*Ctenocephalides felis* and *Ctenocephalides canis*) starts within 48 hours after application of the collar. In addition to the indications listed above an activity against *Pulex irritans* fleas has been demonstrated.

In addition to the tick species listed above activity has been demonstrated against *Ixodes hexagonus*, *I. scapularis* and the non-European tick species *Dermacentor variabilis* and the Australian paralysis tick *I. holocyclus*.

The veterinary medicinal product provides repellent (anti-feeding) activity against the claimed ticks, thus preventing repelled parasites from taking a blood meal and thereby indirectly aids in the reduction of the risk of Canine Vector-Borne Disease transmission.

In addition to the pathogens listed under indications, indirect protection against the transmission of *Babesia canis canis* (by *Dermacentor reticulatus* ticks) has been shown in one laboratory study at day 28 after treatment, and indirect protection against the transmission of *Anaplasma phagocytophilum* (by *Ixodes ricinus* ticks) has been shown in one laboratory study at 2 months after treatment, thereby reducing the risk of diseases caused by these pathogens under the conditions of these studies.

Data from efficacy studies against sand flies (*Phlebotomus perniciosus*) showed a variable sand fly repellent (anti-feeding) efficacy ranging from 65 to 89% for 7-8 months following initial application of the collar. Data from 3 clinical field studies performed in endemic areas indicate a significant reduction in the risk of *Leishmania infantum* transmission by sand flies in treated dogs compared to non-treated dogs. Depending on the infection pressure by sand flies the efficacy in the reduction of the risk of infection with leishmaniosis ranged from 88.3 to 100%.

The collars were able to improve the *Sarcoptes scabiei* infestation in pre-infested dogs leading to a full cure after three months.

NFA-VPS

*Gavin Hall*  
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