SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Seresto Flea and Tick Control 1.25 g + 0.56 g, Collar for Small Dogs ≤ 8 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each collar of 38 cm (12.5 g) contains:

Active substances:

imidacloprid 1.25 g
flumethrin 0.56 g

Excipients:

Qualitative composition of excipients and other constituents
Titanium dioxide (E 171)
Iron oxide black (E 172)
Dibutyladipate
Propylene glycol dicaprylocaprate
Epoxidised soybean oil
Stearic acid
Polyvinyl chloride

Grey, odour free collar embossed with the veterinary medicinal product name on one side.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

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.

The veterainary 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.

The veterinary medicinal product provides indirect protection against the 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.

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

3.3 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.

3.4 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.

3.5 Special precautions for use

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 3.9)

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 5.5.

3.6 Adverse events

Dogs

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

[1] Signs usually resolve within 1 to 2 weeks. In single cases, temporary collar removal is recommended until signs resolve.

[2] 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.
[3] Slight and transient reactions that might occur with initial use.
[4] In these cases, collar removal is recommended.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

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.

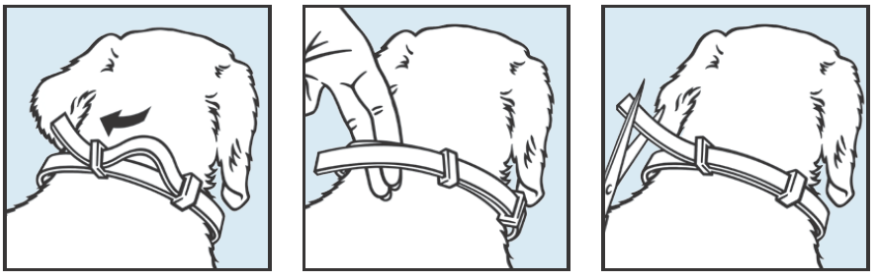
3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Cutaneous use. One collar per animal to be fastened around the neck.
Small dogs up to 8 kg body weight receive one collar of 38 cm length.
For external use only.

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.

This collar is designed with a safety-closure mechanism. In the extremely rare event of a dog being trapped, the animal's own strength is usually sufficient to widen the collar to allow for quick release.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 months period and in 7 week old puppies for a 6 months 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP53AC55

4.2 Pharmacodynamics

Imidacloprid is an ectoparasiticide belonging to the chloronicotinyl group of compounds. Chemically, it can be classified as a chloronicotinyl nitroguanidine. Imidacloprid is active against larval flea stages, adult fleas and lice. Efficacy against fleas (*Ctenocephalides felis and Ctenocephalides canis)* starts within 48 hours after application of the collar. In addition to the indications listed under section 3.2 an activity against *Pulex irritans* fleas has been demonstrated.

Imidacloprid has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS) of the flea. The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergic receptors and the postulated poor penetration through the blood-brain barrier in mammals, it has virtually no effect on the mammalian CNS. Imidacloprid has minimal pharmacological activity in mammals.

Flumethrin is an ectoparasiticide of the synthetic pyrethroid group. According to current knowledge the synthetic pyrethroids interfere with the sodium channel of nerve cell membranes, resulting in a delay in repolarization of the nerve and finally

killing of the parasite. In studies on structure-activity relationship of a number of pyrethroids interference with receptors of a certain chiral conformation was noted thereby causing a selective activity on ectoparasites. No anti-cholinesterase activity was noted with these compounds. Flumethrin is responsible for the veterinary medicinal product's acaricidal activity and also prevents production of fertile eggs by its lethal effect on female ticks. In an *in-vitro* study 5 to 10 % of *Rhipicephalus sanguineus* ticks exposed to a sublethal dose of 4 mg flumethrin/L laid eggs which had a modified appearance (shrivelled, dull and dry) indicating a sterilising effect.

In addition to the tick species listed under section 4.2 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 in section 3.2, 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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Box containing one single 38 cm polyvinyl chloride based collar packed into a PETP/PE bag.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 52127/5106 (GB)
Vm 52127/3041 (NI)

8. DATE OF FIRST AUTHORISATION

04 September 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall

Approved: 17 December 2025