

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Seresto 1.25 g + 0.56 g, collar for cats and dogs \leq 8 kg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

One collar of 38 cm (12.5 g) contains 1.25 g imidacloprid and 0.56 g flumethrin as active substances.

Excipients:

Titanium dioxide (E 171)
Iron oxide black (E 172)
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Collar.
Grey, odour free collar.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats, dogs (\leq 8 kg).
For dogs $>$ 8 kg use Seresto 4.50 g + 2.03 g, collar for dogs $>$ 8 kg (see section 4.9).

4.2 Indications for use, specifying the target species

Cats:

For the treatment and prevention of flea (*Ctenocephalides felis*) infestation for 7 to 8 months.
Protects the animal's immediate surroundings against flea larvae development for 10 weeks.
Seresto can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

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

Ticks already on the cat 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 cat at the time of application is recommended. The prevention of infestations with new ticks starts within two days after application of the collar.

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

Dogs:

For the treatment (*Ctenocephalides felis*) 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.
Seresto can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

The 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. The prevention of infestations with new ticks starts within two days after application of the collar.

The 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.

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

4.3 Contraindications

Do not treat kittens less than 10 weeks of age.

Do not treat puppies less than 7 weeks of age.

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

4.4 Special warnings for each target species

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.

As in all longterm topical 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.

4.5 Special precautions for use

Special precautions for use in animals

The 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 product's flea efficacy gradually decreased, starting in the 5th month.

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

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

As with any veterinary medicinal products, do not allow small children to play with the collar, or to put it into their mouths. Pets wearing the collar should not be allowed to sleep in the same bed as their owners, especially children. People with known sensitivity to the ingredients of the collar should avoid contact with the collar.

Immediately dispose of any remnants or cut-offs of the collar (see section 4.9).

Wash hands with cold water after fitting the collar.

4.6 Adverse reactions (frequency and seriousness)

Occasionally mild behavioural disorders that may include scratching at the application site may be observed in animals that are not used to wearing collars on the first few days after fitting. Ensure that the collar is not fitted too tightly.

Mild application site reactions such as pruritus, erythema and hair loss may occur. These have been reported as rare in dogs and uncommon in cats and usually resolve within 1 to 2 weeks without the need for collar removal. In single cases, a temporary collar removal may be recommended until the symptoms have disappeared.

In very rare cases in dogs and rare cases in cats, application site reactions such as dermatitis, inflammation, eczema or lesions may occur and in these instances, collar removal is recommended.

Also, in rare case in cats, slight and transient reactions as depression, change of food intake, salivation, vomiting and diarrhoea might occur initially. As in other topical applications, allergic contact dermatitis might occur in hypersensitive animals.

The frequency of possible adverse effects is defined using the following convention:

very common (affects more than 1 animal in 10)

common (affects 1 to 10 animals in 100)

uncommon (affects 1 to 10 animals in 1,000)

rare (affects 1 to 10 animals in 10,000)

very rare (affects less than 1 animals in 10,000)

not known (frequency cannot be estimated from the available data).

4.7 Use during pregnancy, lactation or lay

Laboratory studies with either flumethrin or imidacloprid in rats and rabbits have not produced any effects on fertility or reproduction and showed no teratogenic, or foetotoxic effects. However, the safety of the veterinary medicinal product has not been established in target animals during pregnancy and lactation and in the absence of available data, the product is therefore not recommended in pregnant and lactating bitches or queens.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

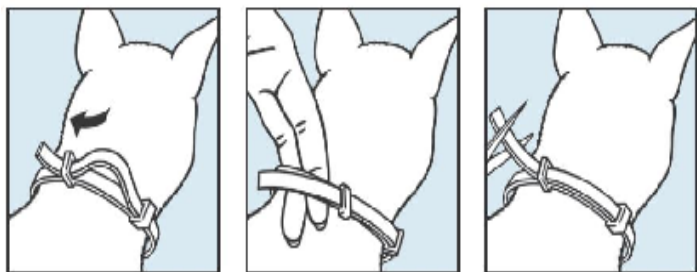
Cutaneous use. One collar per animal to be fastened around the neck.

Cats and small dogs up to 8 kg body weight receive one collar of 38 cm length.

Dogs above 8 kg receive one Seresto collar for dogs > 8 kg of 70 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 kittens/puppies are rapidly growing.

This collar is designed with a safety-closure mechanism. In the unlikely event of a cat being trapped, the cats own strength is sufficient to widen the collar to allow for quick release.

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

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 cats and dogs for an 8 months period and in 10 week old kittens and 7 week old puppies for a 6 months period and no other adverse effects were observed than already described in section 4.6.

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

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticides, insecticides and repellents, pyrethrins and pyrethroids

ATCvet code: QP53AC55 Flumethrin combinations

5.1 Pharmacodynamic properties

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. Activity against *C. felis* starts immediately after application of the collar whereas adequate efficacy against *C. canis* starts within one week after application of the collar.

In addition to the indications listed under section 4.2 an activity against *Ctenocephalides canis* and *Pulex irritans* fleas has been demonstrated.

Imidacloprid has a high affinity for the nicotinic 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 nicotinic 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 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 in cats against *Ixodes hexagonus* and the non-European tick species *Amblyomma americanum* as well as in dogs against *I. hexagonus* *I. scapularis* and the non-European tick species *Dermacentor variabilis* and the Australian paralysis tick *I. holocyclus*.

The 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 Vector-Borne Disease transmission.

For cats, indirect protection against the transmission of *Cytauxzoon felis* (transmitted by *Amblyomma americanum* ticks) has been shown in one laboratory study in a small number of animals at one month after treatment, thereby reducing the risk of diseases caused by this pathogen under the conditions of this study.

For dogs, in addition to the pathogens listed in section 4.2, 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.

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

5.2 Pharmacokinetic properties

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 cat's or 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.

Environmental properties

See section 6.6.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Titanium dioxide (E 171)
Iron oxide black (E 172)
Dibutyladipate
Propylene glycol dicaprylocaprate
Epoxidised soybean oil
Stearic acid
Polyvinyl chloride

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 48 months

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

7 MARKETING AUTHORISATION HOLDER

Bayer Limited
Animal Health Division
The Atrium
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10021/063/003

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st October 2011

10 DATE OF REVISION OF THE TEXT

January 2015