

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Seresto 1.25 g + 0.56 g, collar for cats

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.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

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.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

The veterinary medicinal 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.

3.3 Contraindications

Do not treat kittens less than 10 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 in 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:
Not applicable.

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. Imidacloprid and flumethrin are continuously released from the collar to the skin and fur whilst the collar is being worn.

The veterinary medicinal product may cause hypersensitivity reactions in some people.

People with known hypersensitivity (allergy) to the ingredients of the collar should avoid contact with the veterinary medicinal product.

The veterinary medicinal product may cause skin, eye and respiratory irritation in some people in very rare cases. In case of eye irritation, flush eyes thoroughly with cold water. In case of skin irritation, wash the skin with soap and cold water. If symptoms persist it is recommended to seek medical advice and show the package leaflet or the label to the physician.

Immediately dispose of any remnants or cut-offs of the collar (see section 3.9).

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

Cats:

Uncommon (1 to 10 animals / 1000 animals treated):	Application site reaction ¹ (e.g. Erythema, Hair loss, Pruritus)
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Rare (1 to 10 animals / 10 000 animals treated):	Application site reaction ² (e.g. Dermatitis, Eczema, Haemorrhage, Inflammation, Lesion, Scratching) Behavioural disorder ³ (e.g. Excessive chewing, licking and grooming ⁴ , Hiding, Hyperactivity, Vocalisation) Diarrhoea ⁵ , Hypersalivation ⁵ , Vomiting ⁵ Change in food intake ⁵ Depression ⁵
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Aggression ⁶
Undetermined frequency (cannot be estimated from the available data)	Contact dermatitis ⁷

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

² Collar removal is recommended.

³ May be observed in animals that are not used to wearing collars on the first few days after fitting.

⁴ At the application site.

⁵ Slight and transient reactions that might occur with initial use.

⁶ Ensure that collar is fitted correctly

⁷ Noted in hypersensitive animals.

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 its local representative 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.

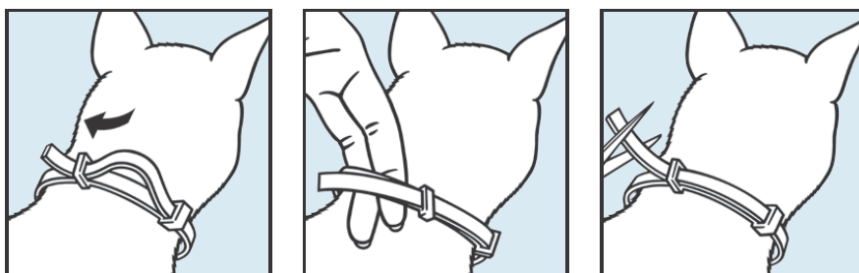
3.9 Administration routes and dosage

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

Cats 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 kittens are rapidly growing.

This collar is designed with a safety-closure mechanism. In the very rare event of a cat being trapped, the animals 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 cats for an 8 months period and in 10 week old kittens for a 6 months period and no other adverse effects were observed than already described in section 3.6.

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. Activity against *C.felis* starts immediately after application of the collar.

In addition to the indications listed under section 3.2 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 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 indications listed under section 3.2 activity against *Ixodes hexagonus* and the non-European tick species *Amblyomma americanum* has been demonstrated.

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 Vector-Borne Disease transmission. 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.

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 cat'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 or two 38 cm polyvinyl chloride based collar(s) individually packed into a PETP/PE bag.

Carton pack containing twelve 38 cm polyvinyl chloride based collars individually packed into a PETP/PE bag.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. (BE, IE, NI)

Veterinary medicinal product not subject to prescription. (AT, DE, ES, FR, IT, LU, NL, PT)

Detailed information on this veterinary medicinal product is available in the [Union Product Database](https://medicines.health.europa.eu/veterinary) (<https://medicines.health.europa.eu/veterinary>).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE**box or carton pack****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Seresto 1.25 g + 0.56 g collar

2. STATEMENT OF ACTIVE SUBSTANCES

Each collar contains: 1.25 g Imidacloprid, 0.56 g Flumethrin.

Grey, odour free collar.

3. PACKAGE SIZE

1 x 38 cm collar

2 x 38 cm collar

12 x 38 cm collar

4. TARGET SPECIES

Cats.

5. INDICATIONS

For products not subject to veterinary prescription

Kills ticks and fleas and repels ticks (“anti-feeding”). 7 - 8 months protection. Water resistant veterinary medicinal product.



Tick



Flea



Larvae

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 logo

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**PETP/PE bag****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Seresto 1.25 g + 0.56 g collar

2. STATEMENT OF ACTIVE SUBSTANCES

Each collar contains: 1.25 g Imidacloprid, 0.56 g Flumethrin

3. TARGET SPECIES

Cats.

4. ROUTES OF ADMINISTRATIONRead the package leaflet before use.
Cutaneous use.**5. WITHDRAWAL PERIODS****6. EXPIRY DATE**

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco logo

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Seresto 1.25 g + 0.56 g, collar for cats

2. Composition

Each grey, odour free collar of 38 cm (12.5 g) contains 1.25 g imidacloprid and 0.56 g flumethrin as active substances.

3. Target species

Cats.

4. Indications for use

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.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).

The veterinary medicinal product has persistent acaricidal (killing) (*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.

5. Contraindications

Do not treat kittens less than 10 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 respectively.

As in all longterm 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:

Not applicable.

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 product, 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. Imidacloprid and flumethrin are continuously released from the collar to the skin and fur whilst the collar is being worn.

The veterinary medicinal product may cause hypersensitivity reactions in some people.

People with known hypersensitivity (allergy) to the ingredients of the collar should avoid contact with the veterinary medicinal product.

The veterinary medicinal product may cause skin, eye and respiratory irritation in some people in very rare cases. In case of eye irritation, flush eyes thoroughly with cold water. In case of skin irritation, wash the skin with soap and cold water. If symptoms persist it is recommended to seek medical advice and show the package leaflet or the label to the physician.

Immediately dispose of any remnants or cut-offs 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 cats for an 8 months period and in 10 week old kittens for a 6 months period and no other adverse effects were observed than already described in section "adverse 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

Cats:

Uncommon (1 to 10 animals / 1000 animals treated):	Application site reaction ¹ (e.g. Erythema (redness), Hair loss, Pruritus (itching))
Rare (1 to 10 animals / 10 000 animals treated):	Application site reaction ² (e.g. Dermatitis, Eczema, Haemorrhage, Inflammation, Lesion, Scratching) Behavioural disorder ³ (e.g. Excessive chewing, licking and grooming ⁴ , Hiding, Hyperactivity, Vocalisation) Diarrhoea ⁵ , Hypersalivation ⁵ (increased salivation), Vomiting ⁵ Change in food intake ⁵ Depression ⁵
Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Aggression ⁶
Undetermined frequency (cannot be estimated from the available data)	Contact dermatitis ⁷

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

² Collar removal is recommended.

³ May be observed in animals that are not used to wearing collars on the first few days after fitting.

⁴ At the application site.

⁵ Slight and transient reactions that might occur with initial use.

⁶ Ensure that collar is fitted correctly.

⁷ Noted in hypersensitive animals.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

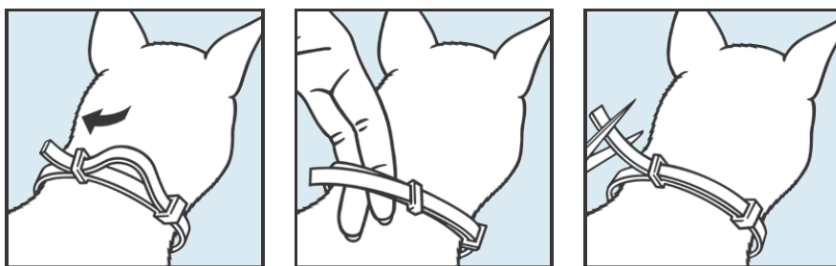
Cutaneous use. Cats receive one collar of 38 cm length. One collar per animal to be fastened around the neck. For external use only.

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.

For multilingual packaging only:

<See illustration of collar use at the end of this leaflet.>



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 are rapidly growing.

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

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 or household waste.

This 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 subject to prescription. (BE, IE, NI)

Veterinary medicinal product not subject to prescription. (AT, DE, ES, FR, IT, LU, NL, PT)

14. Marketing authorisation numbers and pack sizes

Box containing one or two collars; carton containing 12 collars.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

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

Manufacturer responsible for batch release:

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

Local representatives and contact details to report suspected adverse reactions:

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 cat'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.

Activity against *C. felis* starts immediately after application of the collar. In addition to the indications listed above an activity against *Ctenocephalides canis* and *Pulex irritans* fleas has been demonstrated.

In addition to the indications listed above an 8 months activity against *Ixodes hexagonus* and the non-European tick species *Amblyomma americanum* has been demonstrated.

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 Vector-Borne Disease transmission. 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.

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