

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prevexto 4.50 g + 2.03 g, medicated collar for dogs over 8 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 70 cm collar (45 g) contains:

Active substances:

imidacloprid	4.50 g
flumethrin	2.03 g

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Titanium dioxide (E 171)	0.225 g
Black Iron Oxide (E 172)	0.036 g
Brown Iron Oxide (E 172)	0.018 g
Yellow Iron Oxide (E 172)	0.036 g
Di-n-butyl adipate	
Propylene glycol dicaprylocaprate	
Epoxidized soybean oil	
Stearic acid	
Polyvinyl chloride	

Light-grey collar with potential traces of white powder.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (> 8 kg)

3.2 Indications for use for each target species

For dogs with or at risk from mixed infestation by fleas, ticks and lice targeted by each of the combined active substances. The veterinary medicinal product is only indicated when used against the target pathogens at the same time.

Treatment of flea infestation (*Ctenocephalides felis*) and prevention of flea re-infestation (*Ctenocephalides felis*, *C. canis*) due to insecticidal activity for 7 to 8 months.

Protects the animal's immediate surroundings against flea larvae development for 8 months.

The 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 veterinarian.

Prevention of re-infestation with ticks (*Ixodes ricinus*, *Rhipicephalus sanguineus*) through acaricidal (killing) effect and through repellent (anti-feeding) effect from 2 days to 8 months.

Prevention of re-infestation with ticks (*Dermacentor reticulatus*) through acaricidal (killing) effect from 2 days to 8 months.

It is effective against larvae, nymphs and adult ticks.

Reduction of the risk of transmission of the pathogens *Babesia canis vogeli* and *Ehrlichia canis* thereby reducing the risk of canine babesiosis and canine ehrlichiosis for 7 months through acaricidal and repellent effects on the tick vector *Rhipicephalus sanguineus*. The effect is indirect due to product's activity against the vector.

Treatment of infestation by biting/chewing lice (*Trichodectes canis*).

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 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.

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.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy.

The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual.

The use of this product should take into account local information about susceptibility of the target parasites, where available.

In the absence of risk of co-infection by fleas, ticks and lice, a narrow spectrum product should be used.

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

As in all long-term 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.

Fleas can infest pets' beds, sleeping areas and usual resting areas like rugs and sofas. In the event of a massive infestation, these places should be treated with a suitable insecticide and vacuumed regularly.

The possibility that other animals in the same household can be a source of re-infection with fleas, ticks or lice should be considered, and these should be treated as necessary with an appropriate product.

The veterinary medicinal product is water resistant; it remains effective if the animal becomes wet. However, shampooing or prolonged, intense exposure to water should be avoided as the duration of activity may be reduced.

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:

Accidental ingestion of the veterinary medicinal product can induce adverse effects, including neurotoxic effects.

Avoid oral exposure or accidental ingestion, especially by children.

Keep the sachet with the collar in the outer packaging until use and keep the collar in the sachet until use.

Do not allow small children to play with the collar, or to put it into their mouth.

Immediately dispose of any remnants or cut-offs of the collar (see sections 3.9 and 5.5).

In case of oral exposure or accidental ingestion, seek immediate medical advice and show the package leaflet or the label to the physician.

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

People with known hypersensitivity (allergy) to the ingredients of the collar, or iron oxides, should avoid contact with the veterinary medicinal product and the treated animal.

In case of hypersensitive reactions seek medical advice and show the package leaflet or the label to the physician.

The veterinary medicinal product may cause skin, eye and respiratory irritation in some people in very rare cases.

Avoid eye and skin contacts.

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.

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

Avoid prolonged contact with the collar when placing it on the animal and also when it is worn by the treated animal. This especially applies to pregnant women.

Wash hands with cold water after fitting the collar.

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

Special precautions for the protection of the environment:

Imidacloprid and flumethrin may adversely affect aquatic organisms. Dogs wearing the collar should not be allowed to swim in water courses.

Imidacloprid containing products are toxic to honey bees.

3.6 Adverse events

Dogs:

Rare (1 to 10 animals / 10,000 animals treated):	Application site reaction ¹ (e.g. Erythema, Hair loss, Pruritus, Scratching) Behavioural disorder ² (e.g. Excessive chewing, licking and grooming ³ , Hiding, Hyperactivity, Vocalisation) Diarrhoea ⁴ Hypersalivation ⁴ Vomiting ⁴ Change in food intake ⁴ Depression ⁴ Neurological symptoms ⁵ (e.g. Ataxia, Convulsions, Tremor)
Very rare (less than 1 animal in 10,000 animals treated, including isolated reports)	Application site reaction ⁵ (e.g. Dermatitis, Eczema, Haemorrhage, Inflammation, Lesion) Aggression ⁶

- 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.
- ³ At the application site.
- ⁴ Slight and transient reactions that might occur with initial use.
- ⁵ In these cases, collar removal is recommended.
- ⁶ Ensure that collar is fitted correctly.

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 or in breeding animals.

Pregnancy and lactation:

The use is not recommended during pregnancy and lactation.

Laboratory studies with flumethrin in rats and rabbits have not produced teratogenic effects but have shown evidence of foetotoxic effects at maternotoxic doses.

Laboratory studies with imidacloprid in rats and rabbits have not produced any evidence of 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

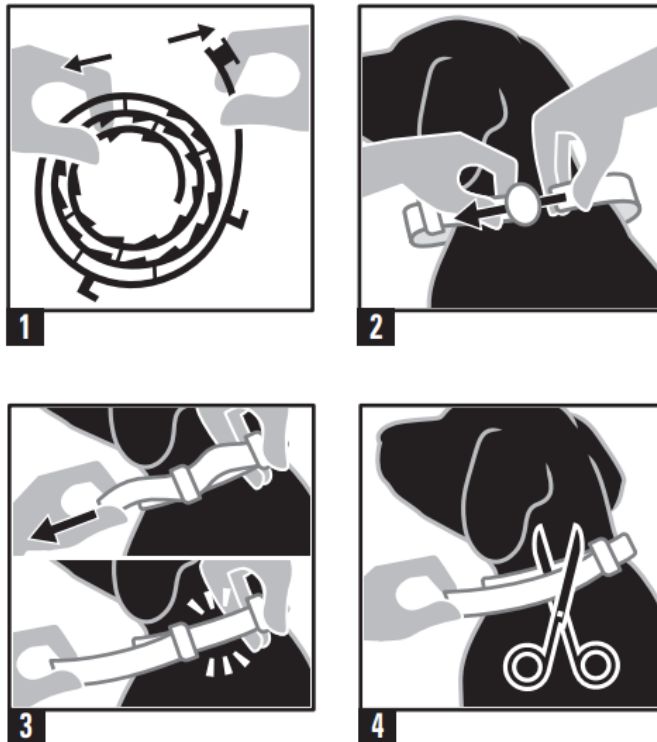
None known.

3.9 Administration routes and dosage

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

Dogs above 8 kg receive one collar for dogs > 8 kg of 70 cm length.

For external use only.



- 1 Remove collar from protective sachet directly before use and apply immediately. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar.
- 2 Adjust the collar around the animal's neck without tightening it too tight.
- 3 As a guide, it should be possible to insert 2 fingers between the collar and the neck.
- 4 Pull excess collar through the first and second loops and cut off any excess length extending beyond 2 cm. Immediately dispose of any remnants or cut-offs of the collar.

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.

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

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

An overdose 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.

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

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.

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 Canine Vector-Borne Disease transmission.

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: 2 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

Carton box containing 1 or 2 collars.

70 cm polyvinyl chloride based collar(s) individually packed into an aluminized plastic bag.

Not all pack sizes may be marketed.

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

VIRBAC

7. MARKETING AUTHORISATION NUMBER

Vm 05653/5078

8. DATE OF FIRST AUTHORISATION

03 July 2025

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

July 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: 27 August 2025