Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Prevexto 1.25 g + 0.56 g, Medicated Collar for Cats
Prevexto 1.25 g + 0.56 g, Medicated Collar for Dogs up to 8 kg
Prevexto 4.50 g + 2.03 g, Medicated Collar for Dogs over 8 kg

Date Created: November 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Prevexto 1.25 g + 0.56 g, Medicated Collar for Cats Prevexto 1.25 g + 0.56 g, Medicated Collar for Dogs up to 8 kg Prevexto 4.50 g + 2.03 g, Medicated Collar for Dogs over 8 kg
Applicant	VIRBAC 1ère avenue 2065 m LID, 06516 Carros, France
Active substance	Flumethrin Imidacloprid
ATC vetcode	QP53AC55
Target species	Cats, Dogs
Indications for use	Prevexto 1.25 g + 0.56 g, Medicated Collar for Cats: For cats with or at risk from mixed infestation by fleas and ticks 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 and prevention of flea re-infestation (*Ctenocephalides felis*) due to insecticidal activity 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), where this has been previously diagnosed by a veterinarian. Prevention of re-infestation with ticks (*Ixodes ricinus*) through acaricidal (killing) effect and through repellent (anti-feeding) effect from 2 days to 8 months.

	Prevention of re-infestation with ticks (*Rhipicephalus turanicus*) through acaricidal (killing) effect from 2 days to 8 months. It is effective against larvae, nymphs and adult ticks. Prevexto 1.25 g + 0.56 g, Medicated Collar for Dogs up to 8 kg & Prevexto 4.50 g + 2.03 g, Medicated Collar for Dogs over 8 kg: 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*).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic hybrid application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10a) as amended.
Date of conclusion of the procedure	27/08/2025

I. SCIENTIFIC OVERVIEW

These are generic hybrid applications in Great Britain (GB) where the reference products are Seresto Flea and Tick Control 1.25 g + 0.56 g, Collar for Cats, Seresto Flea and Tick Control 1.25 g + 0.56 g, Collar for Small Dogs ≤8 kg and Seresto Flea and Tick Control 4.50 g + 2.03 g, Collar for Large Dogs >8 kg. They are considered 'hybrid' applications because plasma bioequivalence cannot be established with regard to the reference medicinal products.

The products are medicated collars and contain imidacloprid and flumethrin as the active substances. The smaller collars (for cats and for dogs ≤8 kg) contain 1.25 g imidacloprid, and 0.56 g flumethrin. The larger collars (for dogs >8 kg) contain 4.50 g imidacloprid, and 2.03 g flumethrin.

The dosage in cats and smaller dogs up to 8kg bodyweight is one 38 cm collar, which should be worn continuously for the 8-month protection period and should be removed after the treatment period. For larger dogs, over 8kg bodyweight, the dosage is one 70 cm collar, which should also be worn continuously for the 8-month protection period and removed after the treatment period.

The distribution category in GB is NFA-VPS, the same as for the reference products.

The products are produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC[1]. The product is safe for the user and for the environment when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy[2] of the product was demonstrated according

[1] SPC – Summary of Product Characteristics.
[2] Efficacy – The production of a desired or intended result.

to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

The quality / safety / efficacy aspects of this product are identical to Seresto Flea and Tick Control collars.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains Flumethrin and Imidacloprid and the excipients Titanium dioxide (E 171), Black Iron Oxide (E 172), Brown Iron Oxide (E 172), Yellow Iron Oxide (E 172), Di-n-butyl adipate, Propylene glycol dicaprylocaprate, Epoxidized soybean oil, Stearic acid and Polyvinyl chloride.

The container consists of aluminised plastic bags. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. The manufacturing method consists of the ingredients being added and mixed to create a liquid component, the solid base material being combined with additives and then blended with the liquid phase to form a compound which is then moulded into the desired product form.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substances are flumethrin and imidacloprid which are established active substances. Imidacloprid is described in the European Pharmacopoeia. Flumethrin is not described in the European Pharmacopoeia and the control monograph is in accordance with the relevant regulatory requirements. The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substance specifications are considered adequate to control the quality of the materials. Batch analytical data demonstrating compliance with these specifications have been provided.

Excipients titanium dioxide, propylene glycol dicaprylocaprate and stearic acid are each monographed in the European Pharmacopoeia and are controlled according to their respective monographs. Iron oxide black, iron oxide brown, and iron oxide yellow are pigments meeting the specifications of food additives. Di-n-butyl-adipate, epoxidised soybean oil and polyvinyl chloride are controlled in accordance with in-house specifications and validated test methods.

Each collar is individually packaged into PET-aluminium-PP sachets and placed into a cardboard box.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the Transmissible Spongiform Encephalopathy (TSE) Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests of the finished product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Control tests on the finished product are those suitable for this formulation.

II.F. Stability

Stability data on the active substances have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years. The sachet should be kept in the outer carton until use.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A. Safety Documentation

Pharmacological Studies

The applicant has provided bibliographical data which shows that imidacloprid is active against larval flea stages, adult fleas and lice. Activity against *C.felis* starts immediately after application of the collar. 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.

Flumethrin interferes with the sodium channel of nerve cell membranes, resulting in a delay in repolarization of the nerve and finally killing of the parasite. Flumethrin is responsible for the product's acaricidal activity and also prevents production of fertile eggs by its lethal effect on female ticks. 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.

The applicant has also provided bibliographical data which shows that 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 animal'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.

Toxicological Studies

As is appropriate for the legal basis of the application, no new toxicological studies were submitted.

User Safety

A user risk assessment was provided in compliance with the relevant guideline which shows absorption rates for imidacloprid of 95% oral and 10% dermal, and for flumethrin of 75% oral and 1.5% dermal.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore, the following applicant's user recommendations are appropriate:

- 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
- 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 oxide, 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.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

The applicant provided a Phase I environmental risk assessment containing sufficient information to conclude that the assessment ends at Phase I as the product will only be used in non-food animals. As a result, environmental exposure will be low and a Phase II ERA was not required.

The products should not cause an unacceptable risk to the environment if used as directed.

IV. CLINICAL DOCUMENTATION

As these are generic hybrid applications, and essential similarity with the reference products have been accepted, efficacy studies are not required.

The efficacy claims, dosing regimens, target animal safety, and pharmacology for the products are equivalent to those of the reference products.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics the benefit/risk profile of the products is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)