Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Gerichtstraße 49
13347 Berlin
(Germany)

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Seresto Foresto 1.25 g + 0.56 g, medicated collar for cats

Seresto Foresto 1.25 g + 0.56 g, medicated collar for dogs ≤ 8 kg

Seresto Foresto 1.25 g + 0.56 g, medicated collar for cats and dogs ≤ 8 kg

Seresto Foresto 4.50 g + 2.03 g, medicated collar for dogs > 8 kg

Date: 02 February 2026

PRODUCT SUMMARY

EU procedure number	DE/V/0348/001-004/DC
Name, strength and pharmaceutical form	Seresto Foresto 1.25 g + 0.56 g, medicated collar for cats Seresto Foresto 1.25 g + 0.56 g, medicated collar for dogs ≤ 8 kg Seresto Foresto 1.25 g + 0.56 g, medicated collar for cats and dogs ≤ 8 kg Seresto Foresto 4.50 g + 2.03 g, medicated collar for dogs > 8 kg
Applicant	Elanco GmbH Heinz-Lohmann-Strasse 4, 27472 Cuxhaven Germany
Active substance(s)	Flumethrin, Imidacloprid
ATC vetcode	QP53AC55
Target species	Cats Cats and Dogs Dogs
Indication for use	***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. 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.

	Dogs: 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 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 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 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. Reduction of the risk of infection with *Leishmania infantum* via transmission by sand flies for up to 8 months. For treatment of biting/chewing lice (*Trichodectes canis*) infestation.

PRODUCT INFORMATION

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Application in accordance with Article 21 of Regulation (EC) 2019/6 as amended.
Date of completion of the original decentralised procedure	24 May 2024
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	Austria, France, Italy, Portugal and Spain
Concerned Member States for subsequent recognition procedure	Strengths 001-002: Netherlands Strength 003: Bulgaria, Czech Republic, Croatia, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Slovenia Strength 004: Bulgaria, Czech Republic, Croatia, Cyprus, Estonia, Greece, Hungary, Latvia, Lithuania, Netherlands, Poland, Romania, Slovakia, Slovenia

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The quality, safety and efficacy aspects of this VMP are identical to Seresto, medicated collar 1.25/0.56 mg resp. Seresto, medicated collar 1.25/0.56 mg resp. Seresto, medicated collar 1.25/0.56 mg or Seresto, medicated collar 4.50/2.03 mg respectively.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

See section 1.

3. SAFETY DOCUMENTATION (safety and residues tests)

See section 1.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

See section 1.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The quality, safety and efficacy aspects of this VMP are identical to Seresto, medicated collar. The data submitted in the dossiers for Seresto, medicated collar demonstrate that when the VMP is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC is available in the Union Product Database (UPD).

This section contains information on significant changes, which have been made after the original procedure, which are important for the quality, safety or efficacy of the VMP.

Sequence of significant variations

Changes to Part 2 of the dossier (quality)

Summary of change (Application number)	Approval date
F.I.d.1.c DE/V/0348/001-004/A/001	02/09/2024

Changes to Part 3 and/or Part 4 of the dossier (safety/efficacy)

Summary of change (Application number)	Supporting information	Approval date
Addition of a QR code and hologram G.I.15.z DE/V/xxxx/WS/179		21/03/2025
Alignment of PI with guidelines G.I.z DE/V/xxxx/WS/197		07/08/2025