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

Actifend 1.25 g + 0.56 g, medicated collar for cats

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

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

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

Date: 12 May 2026

PRODUCT SUMMARY

EU procedure number	DE/V/0355/001-004/DC
Name, strength and pharmaceutical form	Actifend 1.25 g + 0.56 g, medicated collar for cats Actifend 1.25 g + 0.56 g, medicated collar for dogs ≤ 8 kg Actifend 1.25 g + 0.56 g, medicated collar for cats and dogs ≤ 8 kg Actifend 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 cats with or at risk from mixed infestation by fleas and ticks. The veterinary medicinal product is only indicated when use against the target parasites is indicated 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 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.

	Dogs: For dogs with or at risk from mixed infestation by fleas or lice, and ticks or sand flies. The veterinary medicinal product is only indicated when use against parasites targeted by each of the combined active substances is indicated at the same time. Treatment of flea infestation and prevention of flea re-infestation (*Ctenocephalides canis, Ctenocephalides felis)* 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 Flea Allergy Dermatitis (FAD) where it 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. Reduction of the risk of transmission of the pathogen *Leishmania infantum* for up to 8 months thereby reducing the risk of canine leishmaniosis, by repellent activity on sand flies. The effect is indirect due to the product's activity against the vectors. Treatment of infestation by biting lice (*Trichodectes canis*).

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 (EU) 2019/6 as amended.
Date of completion of the original decentralised procedure	12 May 2026
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	Strengths 001-002: France, Italy, Portugal, Spain Strength 003: Czech Republic, Slovakia Strength 004: Czech Republic, France, Italy, Portugal, Slovakia, Spain
Concerned Member States for subsequent recognition procedure	n.a.
Withdrawn CMS during original decentralised subsequent recognition procedure	n.a.

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. Additionally, detailed information on protection periods has only been published in puAR since 09.02.2026.

1. SCIENTIFIC OVERVIEW

The quality, safety and efficacy aspects of this VMP is/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.

None