SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 225 mg chewable tablets for dogs (>5.5–11 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each chewable tablet contains:

Credelio chewable tablets	lotilaner (mg)
for dogs (>5.5–11 kg)	225

Excipients:

Qualitative composition of excipients and other constituents
Cellulose, powdered
Lactose monohydrate
Silicified microcrystalline cellulose
Meat dry flavour
Crospovidone
Povidone K30
Sodium laurilsulfate
Silica, colloidal anhydrous
Magnesium stearate

White to beige round chewable tablets with brownish spots.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For the treatment of flea and tick infestations in dogs.

This veterinary medicinal product provides immediate and persistent killing activity for 1 month for fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Rhipicephalus sanguineus, Ixodes ricinus, I. hexagonus* and *Dermacentor reticulatus*).

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

For reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for one month. The effect is indirect due to the activity of the veterinary medicinal product against the vector.

For the treatment of demodicosis (caused by *Demodex canis*).

For the treatment of sarcoptic mange (*Sarcoptes scabiei* var *canis*).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Parasites need to start feeding on the host to become exposed to lotilaner; therefore the risk of the transmission of parasite borne diseases cannot be completely excluded. Specifically, as an acaricidal effect against *D. reticulatus* may take up to 48 hours, transmission of *B. canis canis* during the first 48 hours cannot be excluded.

3.5 Special precautions for use

Special precautions for safe use in the target species:

All safety and efficacy data have been acquired from dogs and puppies 8 weeks of age and older and 1.3 kg of body weight and greater. Use of this veterinary medicinal product in puppies younger than 8 weeks of age or less than 1.3 kg of body weight should be based on a benefit-risk assessment by the responsible veterinarian.
Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after handling the product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Diarrhoea[1,2], Bloody diarrhoea[1], Vomiting[1,2]; Anorexia[1,2], Lethargy[2]; Polydipsia[1,2]; Ataxia[3], Convulsion[3], Tremor[3]; Pruritus[1,2]; Inappropriate urination[1], Polyuria[1,2], Urinary incontinence[1,2]

[1] Mild and transient

[2] Typically resolve without treatment
[3] Transient in most cases

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 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 during pregnancy, lactation and in breeding dogs.

Pregnancy and lactation:

Use only according to the benefit/risk assessment by the responsible veterinarian.

Laboratory studies in rats have not produced any evidence of teratogenic effects, or any adverse effect on the reproductive capacity of males and females.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

During clinical testing, no interactions between Credelio chewable tablets and routinely used veterinary medicinal products were observed.

3.9 Administration routes and dosage

For oral use.

The veterinary medicinal product should be administered in accordance with the following table to ensure a dose of 20 to 43 mg lotilaner/kg bodyweight.

Body weight of dog (kg)	**Strength and number of tablets to be administered**				
	Credelio 56 mg	Credelio 112 mg	Credelio 225 mg	Credelio 450 mg	Credelio 900 mg
1.3–2.5	1				
>2.5–5.5		1			
>5.5–11.0			1		
>11.0–22.0				1	
>22.0–45.0					1
>45	Appropriate combination of tablets				

Use an appropriate combination of available strengths to achieve the recommended dose of 20– 43 mg/kg.

Credelio is a palatable chewable flavoured tablet. Administer the chewable tablet(s) monthly with or after food.

For the treatment of demodicosis (caused by *Demodex canis*):

Monthly administration of the product for two consecutive months is efficacious and leads to a marked improvement of clinical signs. Treatment should be continued until two negative skin scrapings are obtained one month apart. Severe cases may require prolonged monthly treatments. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

For the treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*): Monthly administration of the product for two consecutive months. Further monthly administration of the product may be required based on clinical assessment and skin scrapings.

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

No adverse reactions were observed following oral administration to puppies aged 8–9 weeks and weighing 1.3–3.6 kg treated with overdoses of up to 5 times the maximum recommended dose (43 mg, 129 mg and 215 mg lotilaner/kg bodyweight) on eight occasions at monthly intervals.

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: QP53BE04

4.2 Pharmacodynamics

Lotilaner, a pure enantiomer from the isoxazoline class, is active against fleas (*Ctenocephalides felis* and *Ctenocephalides canis*), the tick species *Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinus* and *Rhipicephalus sanguineus* as well as *Demodex canis* and *Sarcoptes scabei* var *canis* mites.

Lotilaner is a potent inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in rapid death of ticks and fleas. The activity of lotilaner was not affected by resistance to organochlorines (cyclodienes, e.g. dieldrin), phenylpyrazoles (e.g. fipronil), neonicotinoids (e.g. imidacloprid), formamidines (e.g. amitraz) and pyrethroids (e.g. cypermethrin).

For fleas, the onset of efficacy is within 4 hours of attachment for one month after product administration. Fleas on the animal prior to administration are killed within 6 hours.

For ticks, the onset of efficacy is within 48 hours of attachment for one month after product administration. Existing *I. ricinus* ticks on the animal prior to administration are killed within 8 hours.

The veterinary medicinal product kills existing and newly emerged fleas on dogs before they can lay eggs. Therefore, the product breaks the flea life cycle and prevents environmental flea contamination in areas to which the dog has access.

4.3 Pharmacokinetics

Following oral administration, lotilaner is readily absorbed and peak blood concentration is reached within 2 hours. Food enhances the absorption. The terminal half-life is approximately 4 weeks. This long terminal half-life provides effective blood concentrations for the entire duration of the inter-dosing interval.

The major route of elimination is biliary excretion, and renal excretion is the minor route of elimination (less than 10 % of the dose). Lotilaner is metabolized to a small extent into more hydrophilic compounds, which are observed in faeces and urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

The tablets are packaged in aluminium/ aluminium blisters packaged into an outer cardboard box. Each tablet strength is available in pack sizes of 1, 3, 6 or 18 tablets.

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.

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 GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5006

8. DATE OF FIRST AUTHORISATION

23 April 2017

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

March 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 24 March 2026