SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 112 mg chewable tablets for dogs (>2.5–5.5 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each chewable tablet contains:

Credelio chewable tablets	lotilaner (mg)
for dogs (>2.5–5.5 kg)	112.5

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet.
White to brownish round chewable tablets with brownish spots.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the 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 the treatment of demodicosis (caused by *Demodex canis*).

4.3 Contraindications

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

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

i) Special precautions for use in animals

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.

ii) 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 label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Mild and transient gastrointestinal signs (vomiting; diarrhoea; anorexia) and lethargy have been reported very rarely based on post-marketing safety experience. These signs typically resolve without treatment.
Neurological disorders such as tremor, ataxia or convulsion may occur in very rare cases. In most cases these signs are transient.

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats have not produced any evidence of teratogenic effects, or any adverse effect on the reproductive capacity of males and females. The safety of the veterinary medicinal product in breeding, pregnant and lactating dogs has not been established. Use only according to the benefit-risk assessment of the responsible veterinarian.

4.8 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.

4.9 Amount(s) to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticides for systemic use, isoxazolines.

ATC Vet Code: QP53BE04

5.1 Pharmacodynamic properties

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* mites.

Lotilaner is a potent inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in rapid death of ticks and fleas. In in vitro studies, the activity of lotilaner against some arthropod species 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.

5.2 Pharmacokinetic particulars

Following oral administration, lotilaner is readily absorbed and peak blood concentration is reached at 4 hours. Lotilaner is approximately 10 times more bioavailable when administered with food. The terminal half-life is approximately 4 weeks (harmonic mean). This 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cellulose, powdered
Lactose monohydrate
Silicified microcrystalline cellulose
Meat dry flavour
Crospovidone
Povidone K30
Sodium laurilsulfate
Silica, colloidal anhydrous
Magnesium stearate

6.2 Major Incompatibilities

Not applicable

6.3 Shelf life

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

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 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 or 6 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
Cuxhaven
D-27472
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 52127/5004

9. DATE OF FIRST AUTHORISATION

23 April 2017

10. DATE OF REVISION OF THE TEXT

September 2022

Approved 30 September 2022