PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 56 mg chewable tablets for dogs (1.3–2.5 kg)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

56 mg lotilaner

3. PACKAGE SIZE

1 tablet
3 tablets
6 tablets
18 tablets

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.
Administer with or after food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the blister pack in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBER

Vm 52127/5009

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

56 mg lotilaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 56 mg chewable tablets for dogs (1.3–2.5 kg)
Credelio 112 mg chewable tablets for dogs (>2.5–5.5 kg)
Credelio 225 mg chewable tablets for dogs (>5.5–11 kg)
Credelio 450 mg chewable tablets for dogs (>11–22 kg)
Credelio 900 mg chewable tablets for dogs (>22–45 kg)

Lotilaner

2. COMPOSITION

Each chewable tablet contains:

Credelio chewable tablets	**lotilaner (mg)**
for dogs (1.3–2.5 kg)	56.25
for dogs (>2.5–5.5 kg)	112.5
for dogs (>5.5–11 kg)	225
for dogs (>11–22 kg)	450
for dogs (>22–45 kg)	900

White to beige round chewable tablets with brownish spots.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

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 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*).

5. CONTRAINDICATIONS

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

6. SPECIAL WARNING(S)

Special precautions for safe use in the 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.

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. The administration of this 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 label to the physician.

Pregnancy and lactation:
Laboratory studies in rats have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit/risk assessment by the responsible veterinarian.

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

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.

Overdose:
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.

7. ADVERSE EVENTS

Target species: Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Diarrhoea[1,2], Vomiting[1,2]; Anorexia[1,2], Lethargy[2]; Ataxia[3], Convulsion[3], Tremor[3]

[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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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			1		
>11–22				1	
>22–45					1
>45	Appropriate combination of tablets				

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Credelio chewable tablets	**MA Number**
for dogs (1.3–2.5 kg)	Vm 52127/5009
for dogs (>2.5–5.5 kg)	Vm 52127/5004
for dogs (>5.5–11 kg)	Vm 52127/5006
for dogs (>11–22 kg)	Vm 52127/5007
for dogs (>22–45 kg)	Vm 52127/5010

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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

November 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. CONTACT DETAILS

Marketing authorisation holder:
Elanco GmBH
Heinz-Lohmann Strasse 4
Groden, Cuxhaven
Lower Saxony, 27472
Germany
Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:

Elanco France S.A.S., 26 rue de la Chapelle, 68330 Huningue, France

17. OTHER INFORMATION

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 ricinu*s 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. The activity of lotilaner was not affected by resistance to organochlorines (cyclodienes, e.g. dieldrin), phenylpyrazoles

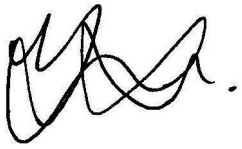
(e.g. fipronil), neonicotinoids (e.g. imidacloprid), formamidines (e.g. amitraz) and pyrethroids (e.g. cypermethrin).

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.

UK (GB and Northern Ireland)
POM-V: To be supplied only on veterinary prescription



Approved: 13 March 2024