

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (dogs)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 900 mg chewable tablets for dogs (>22–45 kg)

lotilaner

2. STATEMENT OF ACTIVE SUBSTANCES

900 mg lotilaner

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

1 tablet

3 tablets

6 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

Administer with or after food.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 52127/5010

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters (dogs)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 900 mg (>22–45 kg)

lotilaner



2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET:

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)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

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

2. 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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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.

4. INDICATION(S)

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).

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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.

The frequency of adverse reactions is defined using the following convention:

- 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).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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.

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 cartonbox and blister after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

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. 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:

Accidental ingestion may cause gastrointestinal disturbances. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after handling the product.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of teratogenic effects. The safety of the veterinary medicinal product in pregnant and lactating dogs has not been established. Use only according to the benefit/risk assessment of 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 in breeding dogs has not been established. Use only according to the benefit-risk assessment of 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 (symptoms, emergency procedures, 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste materials in accordance with local requirements.

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

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.

Each strength of Credelio chewable tablets is available in pack sizes of 1, 3 or 6 tablets. Not all pack sizes may be marketed.

Approved 14 July 2022

