

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 450 mg chewable tablets for dogs (>11–22 kg)

2. STATEMENT OF ACTIVE SUBSTANCES

450 mg lotilaner

3. PACKAGE SIZE

1 tablet

3 tablets

6 tablets

18 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

Administer with or after food.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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 OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5007

15. BATCH NUMBER

Lot {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

450 mg lotilaner
>11–22 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

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)

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 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*).

5. Contraindications

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

6. Special warnings

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.

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. 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 or 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

Dogs:

<i>Very rare (<1 animal / 10 000 animals treated, including isolated reports):</i>
Diarrhoea ^{1,2} , Bloody diarrhoea ¹ , Vomiting ^{1,2} ; Anorexia ^{1,2} , Lethargy ² , Polydipsia (increased thirst) ^{1,2} ; Ataxia ³ , Convulsion ³ , Tremor ³ ; Pruritus (itching) ^{1,2} ; Inappropriate urination ¹ , Polyuria (increased urination) ^{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 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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes 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			
>5.5–11.0			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.

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.

9. Advice on correct administration

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

10. Withdrawal periods

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.

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 applicable national collection systems. These measures should help to protect the environment.

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

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.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
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 ricinus* and *Rhipicephalus sanguineus* as well as *Demodex canis* and *Sarcoptes scabiei* 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.

POM-V

Gavin Hall

Approved: 24 March 2026