Elanco UK AH Limited

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Credelio chewable tablets for dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Ectoparasiticides: For dogs

Active ingredient: Lotilaner

Product: Credelio chewable tablets for dogs

Product index: Credelio chewable tablets for dogs

Incorporating: 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)

Qualitative and quantitative composition

Active substance:

Each chewable tablet contains:

Credelio chewable tablets	**lotilar**
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
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

Pharmaceutical form

White to beige round chewable tablets with brownish spots.

Clinical particulars

Target species

Dogs.

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)*

Contraindications

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

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.aused by *Demodex canis*)

Special precautions for use

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.

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.

iii) Other precautions

Not applicable

Adverse reactions (frequency and seriousness)

Target species: Dogs

Very rare	Diarrhoea1,2, Bloody diarrho
(<1 animal / 10,000 animals treated, including isolated reports):	Anorexia1,2, Lethargy2, Polyc
	Ataxia3, Convulsion3, Tremo
	Pruritis1,2;
	Inappropriate urination1, Pol

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 also the last section of the package leaflet for the respective contact details.

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or 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.

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.

Amounts 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.

	Strength and number of tablets to be administered			
Bodyweight of dog (kg)	Credelio 56 mg	Credelio 112 mg	Credelio 225 mg	Cre
1.3-2.5	1			
>2.5-5.5		1		
>5.5-11.0			1	
>11.0-22.0				1
>22.0-45.0				
>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.

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.

Withdrawal period(s)

Not applicable.

Pharmacological particulars

Pharmacotherapeutic group: ectoparasiticides for systemic use, isoxazolines.

ATCvet code: QP53BE04

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. 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.

Pharmacokinetic particulars

Following oral administration, lotilaner is readily absorbed and peak blood concentration is reached within 2 hours. Food enhances 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.

Pharmaceutical particulars

List of excipients

Cellulose, powdered

Lactose monohydrate

Silicified microcrystalline cellulose

Meat dry flavour

Crospovidone

Povidone K30

Sodium laurilsulfate

Silica, colloidal anhydrous

Magnesium stearate

Incompatibilities

Not applicable.

Shelf life

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

Special precautions for storage

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

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.

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.

Medicines should not be disposed of via wastewater or household waste. Use take-back schemes for medicinal product or waste materials derived thereof in accordance with local requirements and with applicable to the veterinary medicinal product concerned.

Marketing Authorisation Holder (if different from distributor)

Elanco GmbH

Heinz-Lohmann-Str. 4

Groden

27472 Cuxhaven

Germany

Marketing Authorisation Number

NOAH Compendium

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

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

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

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

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

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

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

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

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

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

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation: 25/04/2017

Date of revision of the text

January 2025

Any other information

Veterinary medicinal product subject to prescription

Legal category

Legal category:POM-V

GTIN

GTIN description: Credelio 56mg, 3 tab

GTIN:05014602805562

GTIN description: Credelio 56mg, 6 tab

GTIN:05014602807603

GTIN description: Credelio 112mg, 3 tab

GTIN:05014602805579

GTIN description: Credelio 112mg, 6 tab

GTIN:05014602807610

NOAH Compendium

GTIN description: Credelio 225mg, 3 tab

GTIN:05014602805586

GTIN description: Credelio 225mg, 6 tab

GTIN:05014602807627

GTIN description: Credelio 450mg, 3 tab

GTIN:05014602805593

GTIN description: Credelio 450mg, 6 tab

GTIN:05014602806729