






DOSING GUIDE

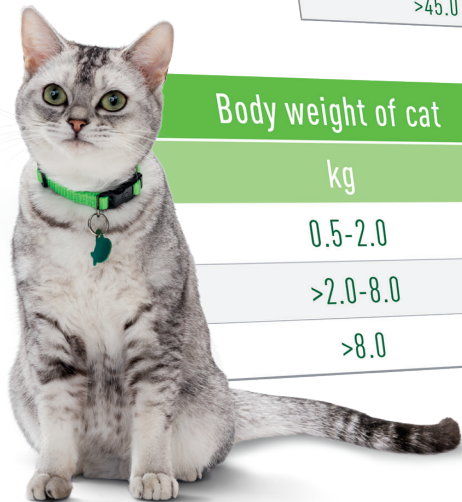
CREDELIO™ (LOTILANER) ACTS FAST WHEN I HAVE TICKS AND FLEAS



Elanco



FAST SPEED OF KILL

Body weight of dog kg	Tablet strength	Number of tablets to be administered
1.3-2.5	56 mg 	One
>2.5-5.5	112 mg 	One
>5.5-11.0	225 mg 	One
>11.0-22.0	450 mg 	One
>22.0-45.0	900 mg 	One
>45.0	Administer the appropriate combination of tablets	



Body weight of cat kg	Tablet strength	Number of tablets to be administered
0.5-2.0	12mg 	One
>2.0-8.0	48mg 	One
>8.0	Administer the appropriate combination of tablets	


Credelio™
 (lotilaner)
TOUGH ON TICKS AND FLEAS
EASY ON US

CREDELIO CHEWABLE TABLETS

Target Species: Dogs and Cats

Active ingredient: Lotilaner

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

CredeLio chewable tablets (dogs)	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

CredeLio chewable tablets (cats)	lotilaner (mg)
for cats (0.5–2.0 kg)	12
for cats (>2.0–8.0 kg)	48

Excipients:

For a full list of excipients, see Pharmaceutical particulars section

CLINICAL PARTICULARS

Indications for use: For the treatment of flea and tick infestations in dogs and cats.

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*).

Cats: This veterinary medicinal product provides immediate and persistent killing activity for 1 month for fleas (*Ctenocephalides felis* and *C. canis*) and ticks (*Ixodes ricinus*).

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).

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.

Special precautions for use

None

Special precautions for use in animals

Dogs: 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.

Cats: Safety and efficacy data has been studied in cats aged 8 weeks and older with a body weight of 0.5 kg or more. Therefore, use of this veterinary medicinal product in kittens younger than 8 weeks of age or less than 0.5 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.

Adverse reactions (frequency and seriousness)

None known.

Use during pregnancy or lactation

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 cats has not been established during pregnancy and lactation. 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.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

- For oral use.

Dogs: 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 900mg
1.3–2.5	1				
>2.5–5.5		1			
>5.5–11			1		
>11–22				1	
>22–45					1
>45	Administer the appropriate combination of tablets				

For dogs more than 45kg Use an appropriate combination of available strengths to achieve the recommended dose of 20– 43 mg/kg.

Cats: The veterinary medicinal product should be administered in accordance with the following table to ensure a dose of 6–24mg of lotilaner /kg of bodyweight

Body weight of cat (kg)	Strength and number of tablets to be administered	
	CredeLio 12 mg	CredeLio 48 mg
0.5–2.0	1	
>2.0–8.0		1
>8 kg	Administer the appropriate combination of tablets	

For cats of more than 8 kg body weight, use an appropriate combination of available strengths to achieve the recommended dose of 6–24 mg/kg.

ADVICE ON CORRECT ADMINISTRATION

Dogs: Administer the chewable tablet(s) monthly with or after food.

Cats: Administer the chewable tablet(s) monthly with food or within 30 minutes of feeding.

PHARMACOLOGICAL PARTICULARS

Pharmacotherapeutic group: ectoparasiticides for systemic use, isoxazolines. ATCvet code: OP53BE04

Pharmacodynamic properties

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), formamides (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 in dogs and 4 hours in cats. Food enhances the absorption in dogs and lotilaner is approximately 10 times more bioavailable when administered with food in cats. The terminal half-life is approximately 4 weeks. This long terminal half-life provides effective blood concentrations for the entire duration of the 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.

List of excipients

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

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: Dogs 2 years, Cats 3 years.

Special precautions for storage

This 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 or 6 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.

CredeLio™ chewable tablets for dogs and CredeLio™ chewable tablets for cats contain lotilaner.

Legal category POM-V UK, POM IE.

For further information call Elanco Animal Health on +44(0)1256 353131 or write to: Elanco Animal Health, Lilly House, Priestley Road, Basingstoke, Hampshire RG24 9NL. For further information consult the product SPC. Refer to the product packaging and leaflets for information about side effects, precautions, warnings and contra-indications. Always seek advice on the use of medicines from the prescriber.

Use medicines responsibly. www.noah.co.uk/responsible. www.apha.ie
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(lotilaner)
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EASY ON US**



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