PACKAGE LEAFLET FOR VETERINARY MEDICINAL PRODUCT

This medicine is dispensed with a veterinarian's prescription only

For veterinary use only

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Credelio 56 mg Veterinary
Credelio 112 mg Veterinary
Credelio 225 mg Veterinary
Credelio 450 mg Veterinary
Credelio 900 mg Veterinary
Chewable tablets for dogs

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

Inactive ingredients: See Section 13

3. **WHAT IS THE MEDICINE INTENDED FOR**

For the treatment of flea and tick infestations in dogs.

This veterinary medicinal product provides immediate and persistent killing activity for one month for fleas (*Ctenocephalides felis* and *C. canis*) as well as 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 ingredient.

This medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

Therapeutic group:

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 fleas and ticks. 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 four hours of attachment for one month after administration of the medicinal product. Fleas found on the animal prior to administration of the medicinal product are killed within six hours.
For ticks, the onset of efficacy is within 48 hours of attachment for one month after administration of the medicinal product. Ticks from the *I. ricinus* species found on the animal prior to administration of the medicinal product are killed within eight hours.
This veterinary medicinal product kills fleas already found on dogs, as well as new fleas, 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.

4. CONTRAINDICATIOS

Do not use in case of hypersensitivity to the active ingredient or to any of the inactive ingredients.

5. ADVERSE REACTIONS

Very rare side effects are reactions that occur in less than 1 in 10,000 animals treated:
Mild and transient gastrointestinal signs (vomiting, diarrhea, anorexia) and lethargy have been reported very rarely based on post-marketing safety findings. These signs typically resolve without treatment.
Neurological problems such as tremor, ataxia (lack of coordination of movement), or convulsions may occur in very rare cases. In most cases these signs are transient.

If you notice any side effects, including those not listed in this package leaflet, or you think that the medicine has not worked, please inform your veterinarian.
You can report side effects to the Ministry of Health by clicking on the link “report side effects resulting from medicinal treatment” found on the homepage of the Ministry of Health website (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

6. TARGET SPECIES

Dogs.

7. METHOD OF ADMINISTRATION AND DOSAGE

Chewable tablets for oral use.

This veterinary medicinal product should be administered in accordance with the following table to ensure a dose of 20 to 43 mg lotilaner/kg body weight.

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.

8. HOW TO USE

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

9. WITHDRAWAL PERIOD

Not applicable.

10. WARNINGS

Special warnings for the target species:

Parasites need to start feeding on the host to become exposed to lotilaner. Therefore, the risk of transmission of parasite-borne diseases cannot be completely excluded.

Special precautions for safe use of the medicine in animals:

All safety and efficacy data have been acquired from adult dogs and puppies eight weeks of age and older and 1.3 kg of body weight and greater. The administration of this product in puppies younger than eight

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 for maintaining the safety of the person handling the medicinal product:
Wash hands after handling the product.
In case of accidental ingestion, seek medical treatment immediately and show the package leaflet or product 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 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 effects 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 eight to nine weeks and weighing 1.3-3.6 kg treated with overdoses of up to five times the maximum recommended dose (43 mg, 129 mg, and 215 mg lotilaner/kg body weight) on eight occasions at monthly intervals.

11. STORAGE INSTRUCTIONS:

Avoid poisoning! This medicine, as well as all other medicines, must be stored in a closed place out of the sight and reach of children, and/or infants, in order to prevent poisoning.
This veterinary medicinal product does not require any special storage conditions. Storage at room temperature is recommended.

Do not use this veterinary medicinal product after the expiry date, which is stated on the carton and the blister pack after the word “EXP”. The expiry date refers to the last day of that month.

12. INSTRUCTIONS FOR THE DISPOSAL OF THE MEDICINAL PRODUCT/ REMNANTS OF THE MEDICINAL PRODUCT AFTER USE

All remnants of the veterinary medicinal product or any waste produced by use of the veterinary medicinal product must be disposed of as poisonous waste. Do not dispose of via wastewater.

13. FURTHER INFORMATION

- In addition to the active ingredient, this medicine also contains:
    - Cellulose, powdered
    - Lactose monohydrate
    - Silicified microcrystalline cellulose
    - Meat dry flavor
    - Crospovidone
    - Povidone K30
    - Sodium lauryl sulfate
    - Silica, colloidal anhydrous
    - Magnesium stearate

- What the medicine looks like and what the package contains:
  White to beige round chewable tablets with brownish spots.
  The package is an aluminum blister pack within a carton.
  The package contains 1, 3, or 6 tablets per box. It may be that not all package sizes are marketed.

- Name and address of the license holder:
  Euromar Ltd., P.O.B. 1064, Ramat HaSharon, 47110

- Name and address of the manufacturer:
  Elanco France S.A.S., 26 Rue de la Chapelle, 68330 Huningue, France

- Registration numbers of the medicine in the Ministry of Health National Drug Registry:

Credelio 56 mg Veterinary:	166 42 35528 00
Credelio 112 mg Veterinary:	166 43 35529 00
Credelio 225 mg Veterinary:	166 44 35530 00
Credelio 450 mg Veterinary:	166 45 35531 00
Credelio 900 mg Veterinary:	166 46 35532 00

This package leaflet was approved in January of 2021.