SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 48 mg chewable tablets for cats (>2.0-8.0 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each chewable tablet contains:

Credelio chewable tablets	lotilaner (mg)
for cats (>2.0-8.0 kg)	48

Excipients:

Qualitative composition of excipients and other constituents
Yeast powder (flavour)
Silicified microcrystalline cellulose
Cellulose, powdered
Lactose monohydrate
Povidone K30
Crospovidone
Sodium laurilsulfate
Vanillin (flavour)
Silica, colloidal anhydrous
Magnesium stearate

White to brownish round chewable tablets with brownish spots.

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

For the treatment of flea and tick infestations on cats.
This veterinary medicinal product provides immediate and persistent killing activity for 1 month against 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 veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

For the treatment of ear mite infestations (*Otodectes cynotis*).

3.3 Contraindications

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

3.4 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.

Acceptable levels of efficacy may not be achieved if the veterinary medicinal product is not administered with food or within 30 minutes after feeding.

Due to insufficient data to support efficacy against ticks in young cats, this product is not recommended for the treatment of ticks in kittens 5 months of age or younger.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperactivity [1,2] Vomiting[2] Ataxia, Muscle tremor Tachypnoea Pruritus [1,2] Anorexia, Lethargy

[1] Mild and transient
[2] Typically resolves without treatment

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

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.

3.8 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.

3.9 Administration routes and dosage

For oral use.

The flavoured veterinary medicinal product should be administered in accordance with the following table to ensure a single dose of 6 to 24 mg lotilaner/kg 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
>8.0	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.

Administer the veterinary medicinal product with food or within 30 minutes after feeding.

For optimal control of tick and flea infestations, the veterinary medicinal product should be administered at monthly intervals and continued throughout the flea and/or tick season based on local epidemiological situations.

For the treatment of ear mites (*Otodectes cynotis*) a single dose of the veterinary medicinal product should be administered.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions were observed following oral administration to kittens aged 8 weeks, weighing 0.5 kg, which were treated with more than 5 times the maximum recommended dose (130 mg lotilaner/kg bodyweight) on eight occasions at monthly intervals.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. <PHARMACOLOGICAL> <IMMUNOLOGICAL> INFORMATION

4.1 ATCvet code:

QP53BE04

4.2 Pharmacodynamics

Lotilaner, a pure enantiomer from the isoxazoline class, is active against fleas (*Ctenocephalides felis and Ctenocephalides canis*), ticks (*Ixodes ricinus*) and ear mites (*Otodectes cynotis*).

Lotilaner is a potent inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in rapid death of ticks and fleas. In *in vitro* studies, the activity of lotilaner against some arthropod species 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 12 hours of attachment for one month after product administration. Fleas on the animal prior to administration are killed within 8 hours.

For ticks, the onset of efficacy is within 24 hours of attachment for one month after product administration. Existing ticks on the animal prior to administration are killed within 18 hours.

The veterinary medicinal product kills existing and newly emerged fleas on cats before they can lay eggs. Therefore, the product breaks the flea life cycle and prevents environmental flea contamination in areas to which the cat has access.

4.3 Pharmacokinetics

Following oral administration, lotilaner is readily absorbed and peak blood concentration is reached at 4 hours. Lotilaner is approximately 10 times more bioavailable when administered with food. The terminal half-life is approximately 4 weeks (harmonic mean).

This 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5008

8. DATE OF FIRST AUTHORISATION

23 April 2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

October 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Approved 13 October 2026

Gavin Hall