1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Chewable tablet.
White to brownish round chewable tablets with brownish spots.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the 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).

4.3 Contraindications

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

4.4 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.
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.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: ectoparasiticides for systemic use, isoxazolines.
ATCvet code: QP53BE04

5.1 Pharmacodynamic properties

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

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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yeast powder (flavour)
Silicified microcrystalline cellulose

Cellulose, powdered
Lactose monohydrate
Povidone K30
Crospovidone
Sodium laurilsulfate
Vanillin (flavour)
Silica, colloidal anhydrous
Magnesium stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

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

6.4. Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 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.

6.6 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.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Lilly House, Priestley Road
Basingstoke
Hampshire
RG24 9NL
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/206/016–21

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25/04/2017

10 DATE OF REVISION OF THE TEXT

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Elanco France S.A.S
26 Rue de la Chapelle
68330 Huningue
FRANCE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF THE MRLs

Not applicable.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Specific pharmacovigilance requirements:

The periodic safety update report (PSUR) cycle should be restarted for submission of 6 monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at 3 yearly intervals.