

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (cats)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

lotilaner

2. STATEMENT OF ACTIVE SUBSTANCES

48 mg lotilaner

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

1 tablet

3 tablets

6 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer with food or within 30 minutes after feeding. Read the package leaflet before use.

Oral use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
Cuxhaven
D-27472
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 52127/5008

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters (cats)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Credelio 48 mg (>2.0 –8.0 kg)



lotilaner

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
Cuxhaven
D-27472
Germany

Manufacturer responsible for batch release:

Elanco France S.A.S., 26 rue de la Chapelle, 68330 Huningue, France

2. 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)

lotilaner

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each chewable tablet contains:

Credelio chewable tablets	lotilaner (mg)
for cats (0.5–2.0 kg)	12
for cats (>2–8.0 kg)	48

White to brownish round chewable tablets with brownish spots.

4. INDICATION(S)

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).

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Vomiting has been reported very rarely based on post marketing safety experience and typically resolves without treatment.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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 localepidemiological situations

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions. Do not use this veterinary medicinal product after the expiry date which is stated on the carton box and blister after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.

Special precautions for use in animals:

All safety and efficacy data have been acquired from cats and kittens 8 weeks of age and older and

0.5 kg of body weight and greater. 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:

Accidental ingestion may cause gastrointestinal disturbances. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

Wash hands after handling the product.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of teratogenic effects. The safety of the veterinary medicinal product in cats has not been established during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Fertility:

Laboratory studies in rats have not produced any evidence of any adverse effect on the reproductive capacity of males and females.

The safety of the veterinary medicinal product in breeding queens has not been established. Use only accordingly 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.

Overdose (symptoms, emergency procedures, antidotes):

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Each strength of Credelio chewable tablets for cats is available in pack sizes of 1, 3 or 6 tablets. Not all pack sizes may be marketed.

Approved 08 September 2022

A handwritten signature in black ink, appearing to be 'M. M. M.', located below the approval date.