PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lotilaner Elanco 12 mg chewable tablets for cats (0.5–2.0 kg)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

12 mg lotilaner

3. PACKAGE SIZE

1 tablet
3 tablets

4. TARGET SPECIES

Cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.
Administer with food or within 30 minutes after feeding.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the blister pack in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

14. MARKETING AUTHORISATION NUMBER

Vm 52127/5044

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {BLISTERS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lotilaner Elanco

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

12 mg lotilaner

0.5–2.0 kg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each chewable tablet contains:

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

White to brownish round chewable tablets with brownish spots.

3. TARGET SPECIES

Cats

4. INDICATIONS FOR USE

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. SPECIAL WARNING(S)

Special precautions for safe use in the 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.

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:
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.

Pregnancy and lactation:
Laboratory studies in rats have not produced any evidence of teratogenic effects. The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according 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 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 lotilaner and routinely used veterinary medicinal products were observed.

Overdose:
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.

7. ADVERSE EVENTS

Target species: Cats

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Vomiting[1]

[1] Typically resolves without treatment

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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	
	Lotilaner Elanco 12 mg	Lotilaner Elanco 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 local epidemiological 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 and blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Lotilaner Elanco chewable tablets	**MA Number**
for cats (0.5–2.0 kg)	Vm 52127/5044
for cats (>2.0–8.0 kg)	Vm 52127/5045

The tablets are packaged in aluminium/aluminium blisters packaged into an outer cardboard box. Each tablet strength is available in pack sizes of 1 or 3 tablets.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:

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

17. 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.

UK (GB and Northern Ireland)

POM-V: To be supplied only on veterinary prescription

Gavin Hall
Approved: 18 September 2025