PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage Chewable 112 mg chewable tablets for dogs (>2.5–5.5 kg)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

112 mg lotilaner

3. PACKAGE SIZE

1 tablet
3 tablets

4. TARGET SPECIES

Dogs greater than 2.5–5.5 kg

5. INDICATION(S)

Kills fleas and ticks

Effective for 1 month

6. ROUTES OF ADMINISTRATION

Oral use.

Administer with or after food.

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
D-27472 Cuxhaven
Germany

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/5047

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

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

NFA-VPS

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage Chewable

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

112 mg lotilaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Advantage Chewable 56 mg chewable tablets for dogs (1.3–2.5 kg)
Advantage Chewable 112 mg chewable tablets for dogs (>2.5–5.5 kg)
Advantage Chewable 225 mg chewable tablets for dogs (>5.5–11 kg)
Advantage Chewable 450 mg chewable tablets for dogs (>11–22 kg)
Advantage Chewable 900 mg chewable tablets for dogs (>22–45 kg)

Iotilaner

2. COMPOSITION

Each chewable tablet contains:

Advantage Chewable	**Iotilaner (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

White to beige round chewable tablets with brownish spots.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

Treatment of flea and tick infestations in dogs.

This veterinary medicinal product provides immediate and persistent killing activity for 1 month for fleas (*Ctenocephalides felis* and *C. canis*) and 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 substance.

The veterinary medicinal product can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD), where this has been previously diagnosed by a veterinary surgeon.

5. CONTRAINDICATIONS

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

6. SPECIAL WARNING(S)

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.

The possibility that other animals in the same household can be a source of re-infection with fleas should be considered, and these should be treated as necessary with an appropriate product.

All stages of fleas can infest the dog's bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning of the control measures, these areas should be treated with a suitable environmental product and then vacuumed regularly.

Special precautions for safe use in the target species:
All safety and efficacy data have been acquired from dogs and puppies 8 weeks of age and older and 1.3 kg of body weight and greater. In the absence of available data, a veterinarian should be consulted before treatment in puppies younger than 8 weeks of age or less than 1.3 kg of body weight.

Inform your veterinary surgeon that you are using this product if s/he provides your dog with any other medication.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after handling the product.

Special precautions for the protection of the environment:
The active substance is mostly excreted in the faeces (poo) and may be toxic to non-target organisms. In order to avoid contamination of the environment, ensure that dog faeces are bagged up and disposed of safely.

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 or lactation. Consult a veterinarian before treatment during pregnancy and lactation.

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 has not been established in breeding dogs. Consult a veterinarian before treatment in breeding dogs.

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 puppies aged 8–9 weeks and weighing 1.3–3.6 kg treated with overdoses of up to 5 times the maximum recommended dose (43 mg, 129 mg and 215 mg lotilaner/kg bodyweight) on eight occasions at monthly intervals.

7. ADVERSE EVENTS

Dogs

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Diarrhoea[1,2], Bloody diarrhoea[1],Vomiting[1,2]; Anorexia[1,2], Lethargy[2], Polydipsia (increased thirst)[1,2] Ataxia[3], Convulsion[3], Tremor[3] Pruritus (itching) [1,2]; Inappropriate urination[1], Polyuria (increased urination)[1,2], Urinary incontinence[1,2]

[1] Mild and transient
[2] Typically resolve without treatment
[3] Transient in most cases

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.
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

For oral use.

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

Body weight of dog (kg)	**Strength and number of tablets to be administered**				
	Advantage Chewable 56 mg	Advantage Chewable 112 mg	Advantage Chewable 225 mg	Advantage Chewable 450 mg	Advantage Chewable 900 mg
1.3–2.5	1				
Greater than 2.5–5.5		1			
Greater than 5.5–11			1		
Greater than 11–22				1	
Greater than 22–45					1
Greater than 45	Appropriate combination of tablets				

For dogs of more than 45 kg body weight, use an appropriate combination of available strengths to achieve the recommended dose of 20–43 mg/kg.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible.

9. ADVICE ON CORRECT ADMINISTRATION

Advantage Chewable is a palatable chewable flavoured tablet. Administer with food or within 30 minutes of feeding.

For optimal control of flea and tick infestation, the product should be administered at monthly intervals throughout the flea and/or tick seasons, 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 not subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Advantage Chewable	**MA Number**
for dogs (1.3–2.5 kg)	Vm 52127/5046
for dogs (>2.5–5.5 kg)	Vm 52127/5047
for dogs (>5.5–11 kg)	Vm 52127/5048
for dogs (>11–22 kg)	Vm 52127/5049
for dogs (>22–45 kg)	Vm 52127/5050

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
D-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 the tick species *Dermacentor reticulatus, Ixodes hexagonus, Ixodes ricinu*s and *Rhipicephalus sanguineus*.

Lotilaner is a potent inhibitor of gamma–aminobutyric acid (GABA)-gated chloride channels, resulting in rapid death of ticks and fleas. 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 4 hours of attachment for one month after product administration. Fleas on the animal prior to administration are killed within 6 hours.

For ticks, the onset of efficacy is within 48 hours of attachment for one month after product administration. Existing *I. ricinus* ticks on the animal prior to administration are killed within 8 hours.

The veterinary medicinal product kills existing and newly emerged fleas on dogs 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.

UK (GB)

NFA-VPS

Gavin Hall
Approved 12 December 2025