ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fluralaner Intervet 45 mg chewable tablets for very small dogs (2-4.5 kg)

Fluralaner Intervet 100 mg chewable tablets for small dogs (> 4.5–10 kg)

Fluralaner Intervet 200 mg chewable tablets for medium-sized dogs (> 10–20 kg)

Fluralaner Intervet 400 mg chewable tablets for large dogs (> 20–40 kg)

Fluralaner Intervet 560 mg chewable tablets for very large dogs (> 40–56 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

Fluralaner Intervet chewable tablets	Fluralaner (mg)
for very small dogs (2–4.5 kg)	45
for small dogs (> 4.5–10 kg)	100
for medium-sized dogs (> 10–20 kg)	200
for large dogs (> 20–40 kg)	400
for very large dogs (> 40–56 kg)	560

Excipients:

ualitative composition of excipients and other constituents	
ork liver flavour	
icrose	
aize starch	
odium laurilsulfate	
isodium pamoate monohydrate	
agnesium stearate	
spartame	
lycerol	
bya-bean oil refined	
acrogol 3350	

Light brown to dark brown chewable tablet with a smooth or slightly rough surface and a practically dome-shaped top surface. Some marbling or specks (or both) may be visible.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For the treatment of tick and flea infestations in dogs.

This veterinary medicinal product is a systemic insecticide and acaricide that provides:

- immediate and persistent flea (Ctenocephalides canis and C. felis) killing activity for 1 month,

- immediate and persistent tick (*Dermacentor reticulatus*, *Ixodes hexagonus*, *I. ricinus* and *Rhipicephalus sanguineus*) killing activity for 1 month.

The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

For reduction of the risk of infection with *Babesia canis canis* via transmission by *D. reticulatus* for 1 month. The effect is indirect due to the veterinary medicinal product's activity against the vector.

For reduction of the risk of infection with *Dipylidium caninum* via transmission by *C. felis* for 1 month. The effect is indirect due to the veterinary medicinal product's activity against the vector.

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 fluralaner; therefore, the risk of the transmission of parasite borne diseases (including *Babesia canis canis* and *D. caninum*) cannot be completely excluded.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use with caution in dogs with pre-existing epilepsy.

In the absence of available data, the veterinary medicinal product should not be used on puppies less than 8 weeks old and/or dogs weighing less than 1.6 kg.

The veterinary medicinal product should not be administered at intervals shorter than 1 month as the safety for shorter intervals has not been tested.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Keep the veterinary medicinal product in the original packaging until use, in order to prevent children from getting direct access to the veterinary medicinal product. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Hypersensitivity reactions in humans have been reported. People with known hypersensitivity to fluralaner and any of the excipients should administer the veterinary medicinal product with caution.

Do not eat, drink or smoke while handling the veterinary medicinal product.

Wash hands thoroughly with soap and water immediately after use of the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals	Digestive tract disorder (e.g. Anorexia, Hypersalivation, Diarrhoea, Emesis);
treated):	Lethargy.
Very rare	Muscle tremor, Ataxia, Convulsion.
(< 1 animal / 10 000 animals treated, including isolated reports):	

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, lactation, or in dogs intended for breeding.

Pregnancy and lactation:

The use is not recommended during pregnancy and lactation.

Fertility:

The use is not recommended in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

Fluralaner is highly bound to plasma proteins and might compete with other highly bound active substances such as non-steroidal anti-inflammatory drugs (NSAIDs) and the coumarin derivative warfarin. Incubation of fluralaner in the presence of carprofen or warfarin in dog plasma at maximum expected plasma concentrations did not reduce the protein binding of fluralaner, carprofen or warfarin.

During clinical field testing, no interactions between the veterinary medicinal product and routinely used veterinary medicinal products were observed.

3.9 Administration routes and dosage

For oral use.

Dose:

The veterinary medicinal product should be administered at a dose of 10–22.5 mg/kg of fluralaner in accordance with the following table:

	Number and strength of tablet to be administered				
Bodyweight (kg)	Fluralaner	Fluralaner	Fluralaner	Fluralaner	Fluralaner
of dog	Intervet	Intervet	Intervet	Intervet	Intervet
	45 mg	100 mg	200 mg	400 mg	560 mg
2 - 4.5	1				

> 4.5 – 10	1			
> 10 – 20		1		
> 20 – 40			1	
> 40 – 56				1

The chewable tablets should not be broken or divided.

For dogs above 56 kg appropriate combinations of chewable tablets should be used. To ensure a correct dosage, body weight (BW) should be determined as accurately as possible.

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

Method of administration:

Administer the veterinary medicinal product at or around the time of feeding.

The veterinary medicinal product is a flavoured chewable tablet. Tablets can be offered to the dog, given with food or placed directly into the mouth. The dog should be observed during administration to confirm that the full tablet is swallowed.

Treatment schedule:

For infestations with fleas and ticks, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

For optimal control of flea and tick infestation, the veterinary medicinal product should be administered at intervals of 1 month.

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

No adverse reactions were observed following oral administration to puppies aged 8 weeks and weighing 1.6–2.9 kg treated with overdoses of up to 5 times the maximum recommended dose (22.5 mg, 67.5 mg and 112.5 mg fluralaner/kg BW) on three occasions 30 days apart.

A comparable veterinary medicinal product, differing in the amount of active substance, was well tolerated in avermectin-sensitive Collie dogs with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at \sim 7.5 times the recommended dose (168 mg/kg BW). No treatment-related clinical signs were observed.

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 INFORMATION

4.1 ATCvet code: QP53BE02

4.2 Pharmacodynamics

Fluralaner is an acaricide and insecticide. It is efficacious against ticks (*Dermacentor reticulatus*, *Ixodes hexagonus*, *I. ricinus* and *Rhipicephalus sanguineus*) and fleas (*Ctenocephalides canis* and *C. felis*) on the dog.

Fluralaner reduces the risk of infection with *Babesia canis canis* via transmission by *D. reticulatus* by killing the ticks within 48 hours, before disease transmission occurs.

Fluralaner reduces the risk of infection with *D. caninum* via transmission by *C. felis* by killing the fleas before disease transmission occurs.

The onset of effect is within 12 hours of attachment for fleas (*C. felis*) and 24 hours of attachment for ticks (*D. reticulatus*).

Fluralaner has a high potency against ticks and fleas by exposure via feeding, i.e., it is systemically active on target parasites. Fluralaner is a potent inhibitor of parts of the arthropod nervous system by acting antagonistically on ligand-gated chloride channels (GABA-receptor and glutamate-receptor).

In molecular on-target studies on insect GABA receptors of flea and fly, fluralaner is not affected by dieldrin resistance. In *in vitro* bio-assays, fluralaner is not affected by proven field resistances against amidines (tick), organophosphates (tick, mite), cyclodienes (tick, flea, fly), macrocyclic lactones (sea lice), phenylpyrazoles (tick, flea), benzophenyl ureas (tick), pyrethroids (tick, mite) and carbamates (mite).

Newly emerged fleas on a dog are killed before viable eggs are produced. An *in vitro* study also demonstrated that very low concentrations of fluralaner stop the production of viable eggs by fleas.

The flea life cycle is broken due to the rapid onset of action and long-lasting efficacy against adult fleas on the animal and the absence of viable egg production.

The product contributes towards the control of the environmental flea populations in areas to which treated dogs have access.

4.3 Pharmacokinetics

After oral administration, fluralaner is readily absorbed, reaching maximum plasma concentrations of approximately 1800 to 4800 ng/mL between a few hours and 3 days post administration.

Oral bioavailability of fluralaner is between 20 and 34%. Fluralaner declines slowly from canine plasma and shows a relatively high volume of distribution (1400 to 2040 mL/kg BW), a low systemic clearance accompanied with a long elimination half-life of approximately 14 days, thus demonstrating persistent effects in the dog during the intended treatment intervals. Fluralaner is mainly excreted via faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.

5.3 Special precautions for storage

Store in the original blister.

5.4 Nature and composition of immediate packaging

Aluminium foil blister(s) sealed with PET aluminium foil lid stock.

Pack sizes:

Cardboard box with 1 blister with 1 chewable tablet.

Cardboard box with 1 blister with 2 chewable tablets.

Cardboard box with 3 individual blisters with 1 chewable tablet each.

Cardboard box with 6 individual blisters with 1 chewable tablet each.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as fluralaner may be dangerous for aquatic invertebrates.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/25/346/001-020

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/06/2025.

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the <u>Union Product Database</u> (<u>https://medicines.health.europa.eu/veterinary</u>).

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ANNEX II OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION
None.

ANNEX III LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE **CARDBOARD BOX** 1. NAME OF THE VETERINARY MEDICINAL PRODUCT Fluralaner Intervet 45 mg chewable tablets for very small dogs (2–4.5 kg) Fluralaner Intervet 100 mg chewable tablets for small dogs (> 4.5–10 kg) Fluralaner Intervet 200 mg chewable tablets for medium-sized dogs (> 10–20 kg) Fluralaner Intervet 400 mg chewable tablets for large dogs (> 20–40 kg) Fluralaner Intervet 560 mg chewable tablets for very large dogs (> 40–56 kg) 2. STATEMENT OF ACTIVE SUBSTANCES Each chewable tablet contains: 45 mg fluralaner 100 mg fluralaner 200 mg fluralaner 400 mg fluralaner 560 mg fluralaner 3. **PACKAGE SIZE** 1 chewable tablet 2 chewable tablets 3 chewable tablets 6 chewable tablets 4. TARGET SPECIES Dogs. 5. **INDICATIONS** 6. ROUTES OF ADMINISTRATION Oral use. 7. WITHDRAWAL PERIODS 8. **EXPIRY DATE** Exp. {mm/yyyy}

SPECIAL STORAGE PRECAUTIONS

9.

Store in the original blister.

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 OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

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EU/2/25/346/001 \ (45\ mg-1\ chewable\ tablet) EU/2/25/346/002 \ (45\ mg-2\ chewable\ tablets) EU/2/25/346/003 \ (45\ mg-3\ chewable\ tablets) EU/2/25/346/004 \ (45\ mg-6\ chewable\ tablets) EU/2/25/346/005 \ (100\ mg-1\ chewable\ tablets) EU/2/25/346/006 \ (100\ mg-2\ chewable\ tablets) EU/2/25/346/007 \ (100\ mg-3\ chewable\ tablets) EU/2/25/346/008 \ (100\ mg-6\ chewable\ tablets)
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EU/2/25/346/009 (200 mg – 1 chewable tablet) EU/2/25/346/010 (200 mg – 2 chewable tablets)

EU/2/25/346/011 (200 mg – 3 chewable tablets)

EU/2/25/346/012 (200 mg – 6 chewable tablets)

EU/2/25/346/013 (400 mg – 1 chewable tablet)

EU/2/25/346/014 (400 mg – 2 chewable tablets)

EU/2/25/346/015 (400 mg – 3 chewable tablets)

EU/2/25/346/016 (400 mg – 6 chewable tablets) EU/2/25/346/017 (560 mg – 1 chewable tablet)

EU/2/25/346/018 (560 mg – 2 chewable tablets)

EU/2/25/346/019 (560 mg – 3 chewable tablets)

EU/2/25/346/020 (560 mg – 6 chewable tablets)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fluralaner Intervet



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each chewable tablet contains:

Fluralaner 45 mg (2–4.5 kg)

Fluralaner 100 mg (> 4.5–10 kg)

Fluralaner 200 mg (> 10–20 kg)

Fluralaner 400 mg (> 20–40 kg)

Fluralaner 560 mg (> 40–56 kg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fluralaner Intervet 45 mg chewable tablets for very small dogs (2–4.5 kg)

Fluralaner Intervet 100 mg chewable tablets for small dogs (> 4.5–10 kg)

Fluralaner Intervet 200 mg chewable tablets for medium-sized dogs (> 10–20 kg)

Fluralaner Intervet 400 mg chewable tablets for large dogs (> 20–40 kg)

Fluralaner Intervet 560 mg chewable tablets for very large dogs (> 40–56 kg)

2. Composition

Each chewable tablet contains:

Active substance:

Fluralaner Intervet chewable tablets	Fluralaner (mg)
for very small dogs (2–4.5 kg)	45
for small dogs (> 4.5–10 kg)	100
for medium-sized dogs (> 10–20 kg)	200
for large dogs (> 20–40 kg)	400
for very large dogs (> 40–56 kg)	560

Light brown to dark brown chewable tablet with a smooth or slightly rough surface and a practically dome-shaped top surface. Some marbling or specks (or both) may be visible.

3. Target species



4. Indications for use

For the treatment of tick and flea infestations in dogs.

This veterinary medicinal product is a systemic insecticide and acaricide that provides:

- immediate and persistent flea (Ctenocephalides canis and C. felis) killing activity for 1 month,
- immediate and persistent tick (*Dermacentor reticulatus*, *Ixodes hexagonus*, *I. ricinus* and *Rhipicephalus sanguineus*) killing activity for 1 month.

The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

For reduction of the risk of infection with *Babesia canis canis* via transmission by *D. reticulatus* for 1 month. The effect is indirect due to the veterinary medicinal product's activity against the vector.

For reduction of the risk of infection with *Dipylidium caninum* via transmission by *C. felis* for 1 month. The effect is indirect due to the veterinary medicinal product's activity against the vector.

5. Contraindications

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

6. Special warnings

Special warnings:

Parasites need to start feeding on the host to become exposed to fluralaner; therefore, the risk of the transmission of parasite borne diseases (including *Babesia canis canis* and *D. caninum*) cannot be completely excluded.

Unnecessary use of antiparasitics or use deviating from the instructions given may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

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

Special precautions for safe use in the target species:

Use with caution in dogs with pre-existing epilepsy.

In the absence of available data, the veterinary medicinal product should not be used on puppies less than 8 weeks old and/or dogs weighing less than 1.6 kg.

The veterinary medicinal product should not be administered at intervals shorter than 1 month as the safety for shorter intervals has not been tested.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Keep the veterinary medicinal product in the original packaging until use, in order to prevent children from getting direct access to the veterinary medicinal product. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Hypersensitivity reactions in humans have been reported. People with known hypersensitivity to fluralaner and any of the excipients should administer the veterinary medicinal product with caution.

Do not eat, drink or smoke while handling the veterinary medicinal product.

Wash hands thoroughly with soap and water immediately after use of the veterinary medicinal product.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy, lactation, or in dogs intended for breeding. The use is not recommended during pregnancy and lactation.

Fertility:

The use is not recommended in breeding animals.

Interaction with other medicinal products and other forms of interaction:

Fluralaner is highly bound to plasma proteins and might compete with other highly bound active substances such as non-steroidal anti-inflammatory drugs (NSAIDs) and the coumarin derivative warfarin. Incubation of fluralaner in the presence of carprofen or warfarin in dog plasma at maximum expected plasma concentrations did not reduce the protein binding of fluralaner, carprofen or warfarin.

During clinical field testing, no interactions between the veterinary medicinal product and routinely used veterinary medicinal products were observed.

Overdose:

No adverse reactions were observed following oral administration to puppies aged 8 weeks and weighing 1.6–2.9 kg treated with overdoses of up to 5 times the maximum recommended dose (22.5 mg, 67.5 mg and 112.5 mg fluralaner/kg body weight) on three occasions 30 days apart.

A comparable veterinary medicinal product, differing in the amount of active substance, was well tolerated in avermectin-sensitive Collie dogs with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at ~7.5 times the recommended dose (168 mg/kg BW). No treatment-related clinical signs were observed.

7. Adverse events

Dogs:

Common

(1 to 10 animals / 100 animals treated):

Digestive tract disorder (e.g. Anorexia, Hypersalivation, Diarrhoea, Vomiting);

Lethargy.

Very rare

(< 1 animal / 10 000 animals treated, including isolated reports):

Muscle tremor, Ataxia (Incoordination), Convulsion.

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: {national system details}.

8. Dosage for each species, routes and method of administration

For oral use.

Dose:

The veterinary medicinal product should be administered at a dose of 10-22.5 mg/kg of fluralaner in accordance with the following table:

	Number and strength of tablet to be administered				
Bodyweight (kg)	Fluralaner	Fluralaner	Fluralaner	Fluralaner	Fluralaner
of dog	Intervet	Intervet	Intervet	Intervet400 mg	Intervet
	45 mg	100 mg	200 mg	intervet400 mg	560 mg
2–4.5	1				
> 4.5–10		1			
> 10–20			1		
> 20–40				1	
> 40–56					1

The chewable tablets should not be broken or divided.

For dogs above 56 kg appropriate combinations of chewable tablets should be used. To ensure a correct dosage, body weight should be determined as accurately as possible. Underdosing could result in ineffective use and may favour resistance development.

9. Advice on correct administration

Method of administration:

Administer the veterinary medicinal product at or around the time of feeding. The veterinary medicinal product is a flavoured chewable tablet. Tablets can be offered to the dog,

given with food or placed directly into the mouth. The dog should be observed during administration to confirm that the full tablet is swallowed.

Treatment schedule:

For infestations with fleas and ticks, the need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

For optimal control of flea and tick infestation, the veterinary medicinal product should be administered at intervals of 1 month.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original blister.

Do not use this veterinary medicinal product after the expiry date which is stated on the cardboard box 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 or household waste.

This veterinary medicinal product should not enter water courses as fluralaner may be dangerous for aquatic invertebrates.

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 applicable national collection systems. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/25/346/001-020

Aluminium foil blister(s) sealed with PET aluminium foil lid stock.

Pack sizes:

Cardboard box with 1 blister with 1 chewable tablet.

Cardboard box with 1 blister with 2 chewable tablets.

Cardboard box with 3 individual blisters with 1 chewable tablet each.

Cardboard box with 6 individual blisters with 1 chewable tablet each.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD month YYYY}

Detailed information on this veterinary medicinal product is available in the <u>Union Product Database</u> (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions: Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien

Tél/Tel: + 32 (0)2 370 94 01

Република България

Тел: + 359 28193749

Česká republika

Tel: + 420 233 010 242

Danmark

Tlf: + 45 44 82 42 00

Deutschland

Tel: +49 (0)8945614100

Eesti

Tel: + 37052196111

Ελλάδα

 $T\eta\lambda$: + 30 210 989 7452

España

Tel: + 34 923 19 03 45

France

Tél: + 33 (0)241228383

Hrvatska

Tel: + 385 1 6611339

Ireland

Tel: + 353 (0) 1 2970220

Lietuva

Tel: + 37052196111

Luxembourg/Luxemburg

Tél/Tel: + 32 (0)2 370 94 01

Magyarország

Tel.: + 36 1 439 4597

Malta

Tel: + 39 02 516861

Nederland

Tel: + 32 (0)2 370 94 01

Norge

Tlf: +47 55 54 37 35

Österreich

Tel: +43 (1) 256 87 87

Polska

Tel.: + 48 22 18 32 200

Portugal

Tel: + 351 214 465 700

România

Tel: +40 21 311 83 11

Slovenija

Tel: + 385 1 6611339

Ísland

Italia

Sími: + 354 535 7000

Slovenská republika Tel: +420 233 010 242

Suomi/Finland

Tel: +39 02 516861

Puh/Tel: + 358 10 2310 750

Κύπρος

Τηλ: +30 210 989 7452

Sverige Tel: + 46 (0)8 5

Tel: +46 (0)8 522 216 60

Latvija

Tel: +37052196111 Tel: +353 (0) 1 2970220

United Kingdom (Northern Ireland)

Manufacturer responsible for batch release:

Intervet Ges.m.b.H., Siemensstrasse 107, 1210 Vienna, Austria

17. Other information

The product contributes towards the control of the environmental flea populations in areas to which treated dogs have access.

Fluralaner reduces the risk of infection with *Babesia canis canis* via transmission by *D. reticulatus* by killing the ticks within 48 hours, before disease transmission occurs.

Fluralaner reduces the risk of infection with *D. caninum* via transmission by *C. felis* by killing the fleas before disease transmission occurs.

The onset of effect is within 12 hours of attachment for fleas (*C. felis*) and 24 hours of attachment for ticks (*D. reticulatus*).