ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BRAVECTO TriUNO chewable tablets for dogs (1.27-2.5 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 2.5-5 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 5 -10 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 10-20 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 20-40 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 40-60 kg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substances:

BRAVECTO TriUNO chewable tablets for dogs	Fluralaner (mg)	Moxidectin (mg)	Pyrantel (as embonate) (mg)
1.27–2.5 kg	25	0.0625	12.5
> 2.5–5 kg	50	0.125	25
> 5–10 kg	100	0.25	50
> 10–20 kg	200	0.5	100
> 20–40 kg	400	1	200
> 40–60 kg	600	1.5	300

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Cellulose, microcrystalline	
Croscarmellose sodium	
Iron oxide red (E172)	
Allura red (E129)	
Indigo carmine aluminium salt (E132)	
Lactose monohydrate	
Hypromellose	
Poloxamer	
Magnesium aluminometasilicate	
Magnesium carbonate, light	
Pork liver flavour	
Silica, colloidal anhydrous	
Magnesium stearate	
Sodium laurilsulfate	
Butylhydroxytoluene (E321)	0.2 mg (1.27 - 2.5 kg) 0.4 mg (> 2.5 - 5 kg) 0.8 mg (> 5 - 10 kg) 1.6 mg (> 10 - 20 kg) 3.2 mg (> 20 - 40 kg) 4.8 mg (> 40 - 60 kg)

Light pink to light brown coloured, mottled, round shaped chewable tablets.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For dogs with, or at risk from, mixed parasitic infestations by ticks or fleas, gastrointestinal nematodes, lungworm and/or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks or fleas and gastrointestinal nematodes is indicated at the same time. The veterinary medicinal product also provides concurrent efficacy for the prevention of heartworm disease, prevention of angiostrongylosis and treatment of *Angiostrongylus vasorum*.

For the treatment of tick and flea infestations on dogs providing immediate and persistent flea (*Ctenocephalides felis* and *C. canis*) and 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.

Treatment of infections with gastrointestinal nematodes of the following species: roundworms (adult stages of *Toxocara canis,* and adult stages of *Toxascaris leonina*) and hookworms (L4, immature adult (L5) and adult stages of *Ancylostoma caninum* and adult stages of *Uncinaria stenocephala*).

Prevention of heartworm disease (caused by *Dirofilaria immitis*).

Prevention of angiostrongylosis (by reduction of the level of infection with immature adult (L5) and adult stages of *Angiostrongylus vasorum*).

Treatment of infections with *Angiostrongylus vasorum* (the causative agent of angiostrongylosis).

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances 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.

Dogs in areas endemic for heartworm (or those which have travelled to endemic areas) may be infected with adult heartworms. No therapeutic effect against adult *D. immitis* has been established. It is therefore recommended, in accordance with good veterinary practice, that all animals 6 months of age or more, living in, or have travelled to, areas where a vector exists, should be tested for existing adult heartworm infections before beginning preventive use with the veterinary medicinal product.

For the treatment of infections with gastrointestinal nematodes, the need for, and the frequency of, re-treatment as well as the choice of the treatment (monosubstance or combination product) should be evaluated by the prescribing veterinarian.

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 product should be based on confirmation of the parasitic species and burden, or of the risk of infections based on epidemiological features, for each individual animal.
In the absence of risk of co-infection with ecto- and endoparasites, a narrow spectrum product should be used.
The possibility that other animals in the same household can be a source of re-infection with ticks, fleas or gastrointestinal nematodes should be considered, and these should be treated as necessary with an appropriate 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 and in dogs with a history of neurological disorders.
In the absence of available data, treatment of puppies less than 8 weeks of age and/or dogs less than 1.27 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.
In (MDR1-/-) dogs, safety of the veterinary medicinal product has only been investigated after single dosing in a laboratory study. At a single observation timepoint, depression was observed in one animal dosed with the maximum recommended treatment dose, and, in a dose-related manner, in more animals at overdoses. The recommended dose should be strictly observed in MDR1 mutant (-/-) dogs with a non-functional P-glycoprotein, which may include, but not necessarily limited to, Collies and related breeds. Please see also section 3.10 'Symptoms of overdose (and where applicable, emergency procedures and antidotes).
The veterinary medicinal product should not be administered at intervals shorter than 1 month as the safety at shorter intervals has not been tested.

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

People with known hypersensitivity to any of the active substances and/or excipients should avoid contact with the veterinary medicinal product.
This veterinary medicinal product is harmful after ingestion. Keep 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.
Do not eat, drink or smoke while handling the veterinary medicinal product.
This veterinary medicinal product may irritate the eyes. Avoid contact with eyes. In case of contact, rinse immediately with plenty of water.
This veterinary medicinal product may irritate the skin or may cause skin sensitization. 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 treated):	Digestive tract disorders (e.g. Diarrhoea, Emesis)[1]

Uncommon (1 to 10 animals / 1,000 animals treated):	Lethargy[2], Hypersalivation[1], Decreased Appetite
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Muscle tremor, Ataxia, Convulsion[3]

1 mild and usually resolves within 1 day

2 mild and usually resolves within 2 days

3 may be serious

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. Laboratory studies with moxidectin in rats and mice have shown evidence of fetotoxic and teratogenic effects.

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

Macrocyclic lactones including moxidectin have been shown to be substrates for p-glycoprotein. Therefore, during treatment with the veterinary medicinal product, other products that are substrates or inhibitors of p-glycoprotein (e.g., cyclosporine, digoxin, doxorubicin, ketoconazole, spinosad) should only be used concomitantly according to the benefit/risk assessment of the responsible veterinarian.

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 orally at a dose of 10-20 mg/kg of fluralaner, 0.025-0.05 mg/kg of moxidectin and 5-10 mg/kg of pyrantel, e.g., as shown in the following table:

Bodyweight (kg) of dog	**Number and strength of chewable tablets to be administered**					
	BRAVECTO TriUNO 25/0.0625/12.5 mg	BRAVECTO TriUNO 50/0.125/25 mg	BRAVECTO TriUNO 100/0.25/50 mg	BRAVECTO TriUNO 200/0.5/100 mg	BRAVECTO TriUNO 400/1/200 mg	BRAVECTO TriUNO 600/1.5/300 mg
1.27–2.5	1					
> 2.5–5		1				

> 5–10			1			
> 10–20				1		
> 20–40					1	
> 40–60						1

The chewable tablet should not be broken or divided.
For dogs above 60 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.

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 ticks, fleas, gastrointestinal nematodes, heartworm and lungworm, the need for and frequency of re-treatments should be based on veterinary advice and should take into account the local epidemiological situation and the animal's lifestyle.

Ticks and fleas:
For optimal treatment and control of flea and tick infestations, the veterinary medicinal product should be administered at intervals of 1 month.

Gastrointestinal nematodes:
For the concurrent treatment of infections with gastrointestinal nematodes, a single dose of the product should be administered. When necessary, dogs can be re-treated at 1-month intervals.

Heartworm:
The veterinary medicinal product kills *Dirofilaria immitis* larvae up to one month after their transmission. Therefore, the veterinary medicinal product should be administered at regular monthly intervals during the time of the year when vectors (mosquitoes) are present. Administration should start in the month after the first expected exposure to the vectors and should continue until 1-month after the last exposure to the vectors. Dogs in areas endemic for heartworm, or dogs which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to administration of the veterinary medicinal product for the concurrent prevention of infection with adult *D. immitis*, the advice provided in section 3.4 should be considered. When replacing another heartworm preventative product in a heartworm prevention programme, the first treatment with the veterinary medicinal product must be given within 1 month of the last dose of the former medication.

Lungworm:
In endemic areas, monthly administration of the veterinary medicinal product will reduce the level of infection with immature adults (L5) and adults of *Angiostrongylus vasorum* in the heart and lungs.
It is recommended that lungworm prevention should be continued until at least 1 month after the last exposure to slugs and snails. For the treatment of infections with *Angiostrongylus vasorum*, a single dose of the product should be administered. When necessary, dogs can be re-treated at 1-month intervals. Seek veterinary advice regarding information on the optimal time to start treatment with this veterinary medicinal product.

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

No adverse reactions were observed in 8-weeks old healthy puppies administered up to 5 times the maximum recommended dose for 7 consecutive monthly administrations.

In a laboratory study, in which the veterinary medicinal product was administered once at 3 and 5 times the maximum recommended dose to dogs with a deficient multidrug-resistance protein 1 (MDR1-/-), within 24 hours, dose related neurological signs (mainly depression and emesis), were observed in all treatment groups. After administration of 5 times the maximum recommended dose, isolated incidences of muscle fasciculations were observed in individual animals.

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: QP54AB52

4.2 Pharmacodynamics

Fluralaner
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.

For fleas, the onset of efficacy is within 24 hours of attachment for 30 days after product administration.

Fluralaner reduces the risk of infection with *Babesia canis* via transmission by *Dermacentor reticulatus* by killing the ticks within 24 hours, before disease transmission occurs.

Fluralaner reduces the risk of infection with *D. caninum* via transmission by *C. felis* by killing the fleas within 24 hours, before disease transmission occurs.

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 fleas and flies, 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 (tick, mite).

Newly emerged fleas on a dog are killed before viable eggs are produced. An *in vitro* study demonstrated that very low concentrations of fluralaner also stop the production of viable eggs by fleas. The flea life cycle is broken, and new infestations are prevented 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.

Moxidectin
Moxidectin, a semisynthetic derivative of nemadectin, belongs to the milbemycin group of macrocyclic lactones (avermectins being the other) and has parasiticidal activity against a range of internal and external parasites, lungworm (*Angiostrongylus vasorum*) and heartworm (*Dirofilaria immitis*)). Moxidectin lacks substantial efficacy against fleas and ticks.

Milbemycins and avermectins have a common mode of action that is based on the binding of ligand-gated chloride channels (glutamate-R and GABA-R). This leads to an increased membrane permeability of nematode and arthropod nerve and/or muscle cells for chloride ions and results in hyperpolarisation, paralysis and death of the parasites. Binding of glutamate-gated chloride channels, which are specific to invertebrates and do not exist in mammals, is considered the main mechanism for the anthelmintic and insecticidal activity.

Pyrantel
Pyrantel belongs to the class of tetrahydropyrimidines and targets nicotinic acetylcholine channel receptors (nAChRs). Selectivity of pyrantel for invertebrate nAChRs is based on high-affinity binding to specific nematode receptor subtypes and a subsequent agonistic mode of action leading to a depolarizing neuromuscular block, which causes muscle contraction, paralysis, and subsequently death of the parasites. Pyrantel lacks activity against muscarinic mAChRs. Pyrantel is an anthelmintic with parasiticidal activity against gastrointestinal parasites (including *T. canis*, *T. leonina*, *A. caninum* and *U. stenocephala*).

4.3 Pharmacokinetics

Fluralaner is readily and rapidly absorbed systemically following oral dosing, reaching mean maximum concentrations in plasma within 17.7 hours (T_{max}) after administration. A fed prandial state of the dog increases the extent of absorption of fluralaner. Fluralaner is slowly eliminated from plasma (half-life of approximately 12 days) via elimination through the faeces with renal clearance being a minor route of elimination.
Moxidectin is readily and rapidly absorbed systemically following oral dosing, reaching mean maximum concentrations in plasma within 3 hours (T_{max}) after administration. Moxidectin is slowly eliminated from plasma (half-life of approximately 16 days) via biliary excretion and elimination through the faeces with minor contributions of metabolic clearance.

Pyrantel is poorly absorbed, and the absorbed portion has a T_{max} of 1.5 hours and half-life of 6 hours. Pyrantel is eliminated through faeces and the small, absorbed portion is eliminated mainly via urine.

For moxidectin and fluralaner, accumulation has been observed after repeated monthly dosing. See sections 3.5 and 3.10.

The pharmacokinetic profiles of fluralaner, moxidectin and pyrantel are not affected by co-administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Store in the original package in order to protect from light.

5.4 Nature and composition of immediate packaging

PVC-oPA –aluminium-oPA-PVC foil blister sealed with PET- aluminium foil lid.
Each blister strip contains one tablet.

Pack sizes:
Cardboard box containing 1 blister strip with 1 tablet
Cardboard box containing 3 blister strips with 1 tablet each
Cardboard box containing 6 blister strips with 1 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.

Moxidectin has been classified as persistent, bioaccumulative and toxic (PBT).

The veterinary medicinal product should not enter water courses as fluralaner and moxidectin may be dangerous for fish and other aquatic organisms.

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/2/24/325/001-018

8. DATE OF FIRST AUTHORISATION

22/11/2024.

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

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

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BRAVECTO TriUNO chewable tablets for dogs (1.27-2.5 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 2.5-5 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 5-10 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 10-20 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 20-40 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 40-60 kg)

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:

25 mg fluralaner / 0.0625 mg moxidectin / 12.5 mg pyrantel (as embonate)
50 mg fluralaner / 0.125 mg moxidectin / 25 mg pyrantel (as embonate)
100 mg fluralaner / 0.25 mg moxidectin / 50 mg pyrantel (as embonate)
200 mg fluralaner / 0.5 mg moxidectin / 100 mg pyrantel (as embonate)
400 mg fluralaner / 1 mg moxidectin / 200 mg pyrantel (as embonate)
600 mg fluralaner / 1.5 mg moxidectin / 300 mg pyrantel (as embonate)

3. PACKAGE SIZE

1 chewable tablet
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}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

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

EU/2/24/325/001 (25 mg / 0.0625 mg / 12.5 mg – 1 tablet)
EU/2/24/325/002 (25 mg / 0.0625 mg / 12.5 mg – 3 tablets)
EU/2/24/325/003 (25 mg / 0.0625 mg / 12.5 mg – 6 tablets)
EU/2/24/325/004 (50 mg / 0.125 mg / 25 mg – 1 tablet)
EU/2/24/325/005 (50 mg / 0.125 mg / 25 mg – 3 tablets)
EU/2/24/325/006 (50 mg / 0.125 mg / 25 mg – 6 tablets)
EU/2/24/325/007 (100 mg / 0.25 mg / 50 mg – 1 tablet)
EU/2/24/325/008 (100 mg / 0.25 mg / 50 mg – 3 tablets)
EU/2/24/325/009 (100 mg / 0.25 mg / 50 mg – 6 tablets)
EU/2/24/325/010 (200 mg / 0.5 mg / 100 mg – 1 tablet)
EU/2/24/325/011 (200 mg / 0.5 mg / 100 mg – 3 tablets)
EU/2/24/325/012 (200 mg / 0.5 mg / 100 mg – 6 tablets)
EU/2/24/325/013 (400 mg / 1 mg / 200 mg – 1 tablet)
EU/2/24/325/014 (400 mg / 1 mg / 200 mg – 3 tablets)
EU/2/24/325/015 (400 mg / 1 mg / 200 mg – 6 tablets)
EU/2/24/325/016 (600 mg / 1.5 mg / 300 mg – 1 tablet)
EU/2/24/325/017 (600 mg / 1.5 mg / 300 mg – 3 tablets)
EU/2/24/325/018 (600 mg / 1.5 mg / 300 mg – 6 tablets)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BRAVECTO TriUNO

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

25 mg / 0.0625 mg / 12.5 mg (1.27-2.5 kg)
50 mg / 0.125 mg / 25 mg (> 2.5-5 kg)
100 mg / 0.25 mg / 50 mg (> 5-10 kg)
200 mg / 0.5 mg / 100 mg (> 10-20 kg)
400 mg / 1 mg / 200 mg (> 20-40 kg)
600 mg / 1.5 mg / 300 mg (> 40-60 kg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

BRAVECTO TriUNO chewable tablets for dogs (1.27-2.5 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 2.5-5 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 5-10 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 10-20 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 20-40 kg)
BRAVECTO TriUNO chewable tablets for dogs (> 40-60 kg)

2. Composition

Each chewable tablet contains:

Active substances:

BRAVECTO TriUNO chewable tablets for dogs	Fluralaner (mg)	Moxidectin (mg)	Pyrantel (as embonate) (mg)
1.27–2.5 kg	25	0.0625	12.5
> 2.5–5 kg	50	0.125	25
> 5–10 kg	100	0.25	50
> 10–20 kg	200	0.5	100
> 20–40 kg	400	1	200
> 40–60 kg	600	1.5	300

Excipients:

BRAVECTO TriUNO chewable tablets for dogs	Butylhydroxytoluene (E321) (mg)
1.27–2.5 kg	0.2
> 2.5–5 kg	0.4
> 5–10 kg	0.8
> 10–20 kg	1.6
> 20–40 kg	3.2
> 40–60 kg	4.8

Light pink to light brown coloured, mottled, round shaped chewable tablets.

3. Target species

Dogs.

4. Indications for use

For dogs with, or at risk from, mixed parasitic infestations by ticks or fleas, gastrointestinal nematodes, lungworm and/or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks or fleas and gastrointestinal nematodes is indicated at the same time. The

veterinary medicinal product also provides concurrent efficacy for the prevention of heartworm disease, prevention of angiostrongylosis and treatment of *Angiostrongylus vasorum*.

For the treatment of tick and flea infestations in dogs providing immediate and persistent flea (*Ctenocephalides felis* and *C. canis*) and 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.

Treatment of infections with gastrointestinal nematodes of the following species: roundworms (adult stages of *Toxocara canis,* and adult stages of *Toxascaris leonina*) and hookworms (L4, immature adult (L5) and adult stages of *Ancylostoma caninum* and adult stages of *Uncinaria stenocephala*).

Prevention of heartworm disease (caused by *Dirofilaria immitis*).

Prevention of angiostrongylosis (by reduction of the level of infection with immature adult (L5) and adult stages of *Angiostrongylus vasorum*).

Treatment of infections with *Angiostrongylus vasorum* (the causative agent of angiostrongylosis).

5. Contraindications

Do not use in cases of hypersensitivity to the active substances 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.

Dogs in areas endemic for heartworm (or those which have travelled to endemic areas) may be infected with adult heartworms. No therapeutic effect against adult *D. immitis* has been established. It is therefore recommended, in accordance with good veterinary practice, that all animals 6 months of age or more, living in, or have travelled to, areas where a vector exists, should be tested for existing adult heartworm infections before beginning preventive use with the veterinary medicinal product.

For the treatment of infections with gastrointestinal nematodes, the need for, and the frequency of, re-treatment as well as the choice of the treatment (monosubstance or combination product) should be evaluated by the prescribing veterinarian.

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 product should be based on confirmation of the parasitic species and burden, or of the risk of infections based on epidemiological features, for each individual animal.
In the absence of risk of co-infection with ecto- and endoparasites, a narrow spectrum product should be used.

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

Special precautions for safe use in the target species:

Use with caution in dogs with pre-existing epilepsy and in dogs with a history of neurological disorders.
In the absence of available data, treatment of puppies less than 8 weeks of age and/or dogs less than 1.27 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.
In (MDR1-/-) dogs, safety of the veterinary medicinal product has only been investigated after single dosing in a laboratory study. At a single observation timepoint, depression was observed in one animal dosed with the maximum recommended treatment dose, and, in a dose-related manner, in more animals at overdoses. The recommended dose should be strictly observed in MDR1 mutant (-/-) dogs with a non-functional P-glycoprotein, which may include, but not necessarily limited to, Collies and related breeds. Please see also the subheading 'Overdose' in section 'Special warnings'.
The veterinary medicinal product should not be administered at intervals shorter than 1 month as the safety at shorter intervals has not been tested.

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

People with known hypersensitivity to any of the active substances and/or excipients should avoid contact with the veterinary medicinal product.
This veterinary medicinal product is harmful after ingestion. Keep 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.
Do not eat, drink or smoke while handling the veterinary medicinal product.
This veterinary medicinal product may irritate the eyes. Avoid contact with eyes. In case of contact rinse immediately with plenty of water.
This veterinary medicinal product may irritate the skin or may cause skin sensitization. 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. Laboratory studies with moxidectin in rats and mice have shown evidence of fetotoxic and teratogenic effects. 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:
Macrocyclic lactones including moxidectin have been shown to be substrates for p-glycoprotein. Therefore, during treatment with the veterinary medicinal product, other products that are substrates or inhibitors of p-glycoprotein (e.g., cyclosporine, digoxin, doxorubicin, ketoconazole, spinosad) should only be used concomitantly according to the benefit/risk assessment of the responsible veterinarian.

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 in 8-weeks old healthy puppies administered up to 5 times the maximum recommended dose for 7 consecutive monthly administrations.
In a laboratory study, in which the veterinary medicinal product was administered once at 3 and 5 times the maximum recommended dose to dogs with a deficient multidrug-resistance protein 1 (MDR1-/-), within 24 hours, dose related neurological signs (mainly depression and emesis), were

observed in all treatment groups. After administration of 5 times the maximum recommended dose, isolated incidences of muscle fasciculations were observed in individual animals.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated)
Digestive tract disorders (e.g., Diarrhoea, Vomiting) [1]
Uncommon (1 to 10 animals / 1,000 animals treated):
Lethargy [2], Hypersalivation [1], Decreased Appetite
Very rare (<1 animal / 10,000 animals treated, including isolated reports)
Muscle tremor, Ataxia, Convulsion[3]

[1] mild and usually resolves within 1 day
[2] mild and usually resolves within 2 days
[3] may be serious

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 orally at a dose of 10-20 mg/kg of fluralaner, 0.025-0.05 mg/kg of moxidectin and 5-10 mg/kg of pyrantel, e.g., as shown in the following table:

Bodyweight (kg) of dog	**Number and strength of chewable tablets to be administered**					
	BRAVECTO TriUNO 25/0.0625/12.5 mg	BRAVECTO TriUNO 50/0.125/25 mg	BRAVECTO TriUNO 100/0.25/50 mg	BRAVECTO TriUNO 200/0.5/100 mg	BRAVECTO TriUNO 400/1/200 mg	BRAVECTO TriUNO 600/1.5/300 mg
1.27–2.5	1					
> 2.5–5		1				
> 5–10			1			
> 10–20				1		
> 20–40					1	
> 40–60						1

The chewable tablet should not be broken or divided.
For dogs above 60 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 ticks, fleas, gastrointestinal nematodes, heartworm and lungworm, the need for and frequency of re-treatments should be based on veterinary advice and should take into account the local epidemiological situation and the animal's lifestyle.

Ticks and fleas:
For optimal treatment and control of flea and tick infestations, the veterinary medicinal product should be administered at intervals of 1 month.

Gastrointestinal nematodes:
For the concurrent treatment of infections with gastrointestinal nematodes, a single dose of the product should be administered. When necessary, dogs can be re-treated at 1-month intervals.

Heartworm:
The veterinary medicinal product kills *Dirofilaria immitis* larvae up to one month after their transmission. Therefore, the veterinary medicinal product should be administered at regular monthly intervals during the time of the year when vectors (mosquitoes) are present. Administration should start in the month after the first expected exposure to the vectors and should continue until 1-month after the last exposure to the vectors.
Dogs in areas endemic for heartworm, or dogs which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to administration of the veterinary medicinal product for the concurrent prevention of infection with adult *D. immitis*, the advice provided in section 'Special warnings' should be considered. When replacing another heartworm preventative product in a heartworm prevention
programme, the first treatment with the veterinary medicinal product must be given within 1 month of the last dose of the former medication.

Lungworm:
In endemic areas, monthly administration of the veterinary medicinal product will reduce the level of infection with immature adults (L5) and adults of *Angiostrongylus vasorum* in the heart and lungs.
It is recommended that lungworm prevention should be continued until at least 1 month after the last exposure to slugs and snails. For the treatment of infections with *Angiostrongylus vasorum*, a single dose of the product should be administered. When necessary, dogs can be re-treated at 1-month intervals. Seek veterinary advice regarding information on the optimal time to start treatment with this veterinary medicinal product.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original package in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the packaging 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.

Moxidectin has been classified as persistent, bioaccumulative and toxic (PBT). The veterinary medicinal product should not enter water courses as fluralaner and moxidectin may be dangerous for fish and other aquatic organisms.

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. 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/2/24/325/001-018

PVC-oPA –aluminium-oPA-PVC foil blister sealed with PET- aluminium foil lid.
Each blister strip contains one tablet.

Pack sizes:
Cardboard box containing 1 blister strip with 1 tablet
Cardboard box containing 3 blister strips with 1 tablet each
Cardboard box containing 6 blister strips with 1 tablet each

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

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

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Lietuva
Tel: + 37052196111

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
Τηλ: + 30 210 989 7452

España
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France
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Hrvatska
Tel: + 385 1 6611339

Ireland
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Italia
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Κύπρος
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Luxembourg/Luxemburg
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Malta
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Nederland
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Norge
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Österreich
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Polska
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Portugal
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România
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Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: +420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

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.

For fleas, the onset of efficacy is within 24 hours of attachment for 30 days after product administration.

Fluralaner reduces the risk of infection with *Babesia canis* via transmission by *Dermacentor reticulatus* by killing the ticks within 24 hours, before disease transmission occurs.

Fluralaner reduces the risk of infection with *D. caninum* via transmission by *C. felis* by killing the fleas within 24 hours, before disease transmission occurs.