1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto 112.5 mg Chewable Tablets Veterinary
Bravecto 250 mg Chewable Tablets Veterinary
Bravecto 500 mg Chewable Tablets Veterinary
Bravecto 1000 mg Chewable Tablets Veterinary
Bravecto 1400 mg Chewable Tablets Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Each chewable tablet contains:

Bravecto chewable tablets veterinary	**Fluralaner (mg)**
for very small dogs (2–4.5 kg)	112.5
for small dogs (>4.5–10 kg)	250
for medium-sized dogs (>10–20 kg)	500
for large dogs (>20–40 kg)	1000
for very large dogs (>40–56 kg)	1400

Excipients:

Qualitative composition of excipients and other constituents
Pork liver flavor
Sucrose
Maize starch
Sodium laurylsulfate
Disodium pamoate monohydrate
Magnesium stearate
Aspartame
Glycerol
Soya-bean oil (0.1% BHT stabilized)
Macrogol 3350

Chewable tablet.
Light to dark brown tablet with a smooth or slightly rough surface and circular shape. Some marbling, speckles or both may be visible.

3. CLINICAL INFORMATION

3.1 Target species

Dog

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 felis*) killing activity for 12 weeks,
- immediate and persistent tick killing activity for 12 weeks for *Ixodes ricinus, Dermacentor reticulatus* and *D. variabilis,*
- immediate and persistent tick killing activity for 8 weeks for *Rhipicephalus sanguineus*.

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance. The onset of effect is within 8 hours of attachment for fleas (*C. felis*) and 12 hours of attachment for ticks (*I. ricinus*).

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

For the treatment of demodicosis caused by *Demodex canis*.
For the treatment of sarcoptic mange (*Sarcoptes scabiei* var. *canis*) infestation.

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 cannot be completely excluded.
Unnecessary use of antiparasitics or use deviating from the instructions given in the physician leaflet 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-infection with parasites 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 2 kg.
The veterinary medicinal product should not be administered at intervals shorter than 8 weeks 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.
Hypersensitivity reactions in humans have been reported.
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

Dog:

Common (1 to 10 animals / 100 animals treated):	Gastrointestinal effects (such as Anorexia, Hypersalivation, Diarrhoea, Emesis) [#].
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Lethargy; Pruritus; Muscle tremor, Ataxia, Convulsion.

[#] mild and transient

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product in breeding, pregnant and lactating dogs has been demonstrated. Can be used in breeding, pregnant and lactating dogs.

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.

The veterinary medicinal product should be administered in accordance with the following table (corresponding to a dose of 25–56 mg fluralaner/kg bodyweight within one weight band):

Bodyweight of dog (kg)	**Strength and number of tablets to be administered**				
	Bravecto 112.5 mg	Bravecto 250 mg	Bravecto 500 mg	Bravecto 1000 mg	Bravecto 1400 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 body weight, use a combination of two tablets that most closely matches the bodyweight.
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 chewable tablet is well accepted by most dogs. If the tablet is not taken up voluntarily by the dog it can also be given with food or directly into the mouth. The dog should be observed during administration to confirm that the 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 infestation, the veterinary medicinal product should be administered at intervals of 12 weeks. For optimal control of tick infestation, the timing of retreatment depends on the tick species. See section 3.2.
For the treatment of *Demodex canis* mite infestations, a single dose of the product should be administered. As demodicosis is a multi-factorial disease, it is advisable to also treat any underlying disease appropriately.
For the treatment of sarcoptic mange infestations (*Sarcoptes scabiei* var. *canis*), a single dose of the veterinary medicinal product should be administered. The need for and frequency of re-treatment should be in accordance
with the advice of the prescribing veterinarian.

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

No adverse reactions were observed following oral administration to puppies aged 8–9 weeks and weighing 2.0–3.6 kg treated with overdoses of up to 5 times the maximum recommended dose (56 mg, 168 mg and 280 mg fluralaner/kg bodyweight) on three occasions at shorter intervals than recommended (8-week intervals).

There were no findings on reproductive performance and no findings of concern on offspring viability when fluralaner was administered orally to Beagle dogs at overdoses of up to 3 times the maximum recommended dose (up to 168 mg/kg body weight of fluralaner).

The veterinary medicinal product was well tolerated in Collies with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at 3 times the recommended dose (168 mg/kg body weight). 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 (*Ixodes* spp*., Dermacentor* spp. and *Rhipicephalus sanguineus*), fleas (*Ctenocephalides* spp.), *Demodex canis* mites and sarcoptic mange (*Sarcoptes scabiei* var. *canis*) on the dog.

The onset of effect is within 8 hours of attachment for fleas (C. felis) and 12 hours of attachment for I. ricinus and 48 hours for D. reticulatus ticks.

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).

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

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.

4.3 Pharmacokinetics

Following oral administration, fluralaner is readily absorbed reaching maximum plasma concentrations within 1 day. Food enhances the absorption. Fluralaner is systemically distributed and reaches the highest concentrations in fat, followed by liver, kidney and muscle. The prolonged persistence and slow elimination from plasma ($t_{1/2}$ = 12 days) and the lack of extensive metabolism provide effective concentrations of fluralaner for the duration of the inter-dosing interval. Individual variation in C_{max} and $t_{1/2}$ was observed. The major route of elimination is the excretion of unchanged fluralaner in faeces (~90% of the dose). Renal clearance is the minor route of elimination.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

The expiry date of the product is indicated on the packaging materials.

5.3 Special precautions for storage

Store below 25°C.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 aluminium foil blister sealed with PET aluminium foil lid stock containing 1, 2 or 4 chewable tablets.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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. MANUFACTURER

Intervet GesmbH, Vienna, Austria

7. MARKETING AUTHORISATION HOLDER

Intervet Israel Ltd.
Neve Ne'Eman Industrial Park
Hod HaSharon 45240

8. LICENSES NUMBERS

Bravecto 112.5 mg Chewable Tablets Veterinary - 156-03-34344-00
Bravecto 250 mg Chewable Tablets Veterinary - 156-04-34346-00
Bravecto 500 mg Chewable Tablets Veterinary - 156-05-34347-00
Bravecto 1000 mg Chewable Tablets Veterinary - 156-06-34348-00
Bravecto 1400 mg Chewable Tablets Veterinary - 156-07-34349-00

Revised in July 2025 according to MOHs guidelines.