Veterinary product User Leaflet

The product is dispensed with a veterinarian's prescription only

For veterinary use only

1. NAME OF THE 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. COMPOSITION:

Active substance:

Each chewable tablet contains:

Product	Fluralaner (mg)
Bravecto 112.5 mg Chewable Tablets Veterinary – for very small dogs (2-4.5 kg)	112.5
Bravecto 250 mg Chewable Tablets Veterinary – for small dogs (>4.5-10 kg)	250
Bravecto 500 mg Chewable Tablets Veterinary – for medium-sized dogs (>10-20 kg)	500
Bravecto 1000 mg Chewable Tablets Veterinary – for large dogs (>20-40 kg)	1,000
Bravecto 1400 mg Chewable Tablets Veterinary – for very large dogs (>40-56 kg)	1,400

See list of excipients in section 13 - "Further Information".

3. WHAT IS THE MEDICINAL PRODUCT INTENDED FOR:

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 killing activity for 12 weeks of ticks of types *Ixodes ricinus, Dermacentor reticulatus, Dermacentor variabilis*.
- immediate and persistent killing activity for 8 weeks of tick type *Rhipicephalus sanguineus*.

Fleas and ticks should attach to the host and commence feeding in order to be exposed to the active substance.

The onset of the effect of the product is within 8 hours of attachment of the fleas (*C. felis*) and within 12 hours of attachment of ticks (*I. ricinus*).

The product can be used as part of a treatment and prevention strategy for flea allergy dermatitis (FAD).

Therapeutic group: Ectoparasiticides for systemic use.

4. CONTRAINDICATIONS:

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

5. ADVERSE REACTIONS:

Common side effects (1-10 in 100 animals treated) in clinical trials (1.6% of treated dogs) included mild and transient gastrointestinal effects such as: diarrhea, vomiting, inappetence, and drooling.

Lethargy, muscle tremor, ataxia and convulsions have been reported very rarely (less than 1 animal in 10,000 animals treated) in spontaneous reports.

Most reported adverse reactions were self-limiting and of short duration.

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 inform your veterinary surgeon.

Side effects can be reported to the Ministry of Health by clicking on the "Reporting side effects due to drug treatment" link found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

6. TARGET SPECIES:
Dogs

7. MODE OF ADMINISTRATION AND DOSAGE:
For oral use:
Bravecto should be administered in accordance with the following table: (corresponding to a dosage of 25–56 mg fluralaner/kg bodyweight within one weight band):

Bodyweight of dog (kg)	**Strength and number of tablets to administer**				
	Bravecto 112.5 mg	Bravecto 250 mg	Bravecto 500 mg	Bravecto 1000 mg	Bravecto 1400 mg
2-4.5	I				
>4.5-10		I			
>10-20			I		
>20-40				I	
>40-56					I

For dogs weighing more than 56 kg, use a combination of two tablets that most closely correspond to the dog's weight.

8. HOW TO USE THE PRODUCT:
Do not divide or break the chewable tablets.
Administer the chewable tablets at or around the time of feeding.
Bravecto are chewable tablets usually well accepted by dogs. If the dog does not voluntarily take the tablet, it can also be given with food or directly into the mouth. Observe the dog during administration to confirm that the tablet is indeed swallowed.

Treatment schedule:
For optimal prevention of flea infestation, administer the product at intervals of 12 weeks. For optimal prevention of tick infestation, the timing of retreatment depends on the type of tick (see section 3).

9. WITHDRAWAL PERIOD:
Not applicable.

10. WARNINGS:

- Special warnings regarding use in the target animal

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 excluded.

- Special warnings regarding the safety of use of the medicinal product in animals

Use with caution in dogs with pre-existing epilepsy.

In the absence of available data, do not use this product in puppies younger than 8 weeks old and/or dogs weighing less than 2 kg.
Do not administer the product at intervals shorter than 8 weeks, as the safety for short intervals has not been tested.

- Special warnings regarding the safety of the person handling the medicinal product

Keep the product in its original package until use, in order to keep out of reach of children.
Hypersensitivity reactions in humans have been reported.
Do not eat, drink or smoke while handling the product.
Wash hands thoroughly with soap and water immediately after use of the product.

- Pregnancy and breastfeeding

Can be used in breeding, pregnant and lactating dogs.

Interaction with other medicinal products and other forms of interaction

Fluralaner highly bound to plasma proteins and might compete with other highly bound active substances such as non-steroidal anti-inflammatory drugs (NSAIDs) and coumarin-derived 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.
No interactions between Bravecto and other medicinal products routinely administered to dogs were observed during clinical trials.

- Overdose

Safety was demonstrated in breeding, pregnant and lactating animals treated with overdoses of up to 3 times the maximum recommended dose.

Safety was demonstrated in puppies aged 8 – 9 weeks and weighing 2.0 – 3.6 kg treated with overdoses of up to 5 times the maximum recommended dose on three occasions at shorter intervals than recommended (8-weeks).

Collies with a mutated gene encoding the multidrug-resistance protein 1 (MDR1 -/-) responded well to the veterinary medicinal product following a single oral administration of 3 times the recommended dosage.

- Major incompatibilities:
  None known.

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicinal product and any other medicinal products should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use this product after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions
  Store below 25ºC.

12. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINAL PRODUCT/REMNANTS OF THE MEDICINAL PRODUCT AFTER USE:

Any unused veterinary medicinal product or waste materials derived from use of the veterinary medicinal product should be disposed of as toxic waste; do not discard in waste water.

13. FURTHER INFORMATION:

- In addition to the active substance(s), this product also contains:
  Super premium in powder for dog flavor
  Sucrose
  Maize starch
  Sodium lauryl sulfate
  Disodium pamoate monohydrate
  Magnesium stearate
  Aspartame
  Glycerol
  Soya-bean oil (0.1% BHT stabilized)

Macrogol 3350

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

- What the product looks like and the contents of the package:
  Chewable tablets.
  Light to dark brown tablets with a smooth or slightly rough surface and circular shape.
  Some marbling, speckles or both may be visible.
  Cardboard box with an aluminum foil blister, sealed with PET aluminum.

- Package size:
  Containing 1, 2 or 4 chewable tablets. Not all sizes may be marketed.

- **License holder and address:**
  Intervet Israel Ltd., Neve Ne'eman Industrial Zone, Hod Hasharon 45240.

- **Manufacturer and address:**
  Intervet GesmbH, Siemensstrasse 107, 1210 Vienna, Austria

- Revised in February 2021 according to MOHs guidelines.

- **Registration number of the product in the National Drug Registry of the Ministry of Health:**

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