**Patient Leaflet for Veterinary Medicinal Product**
This product is marketed with a veterinarian's prescription only
For use in animals only

## 1. NAME OF THE MEDICINAL PRODUCT:

**Bravecto 112.5 mg Spot-on Solution Veterinary Dogs**

**Bravecto 250 mg Spot-on Solution Veterinary Dogs**

**Bravecto 500 mg Spot-on Solution Veterinary Dogs**

**Bravecto 1000 mg Spot-on Solution Veterinary Dogs**

**Bravecto 1400 mg Spot-on Solution Veterinary Dogs**

Solution for topical use.

## 2. COMPOSITION:

Active substance:
Each ml contains 280 mg Fluralaner.

Each pipette contains:

| Product | Pipette content (ml) | Fluralaner (mg) |
|---|---|---|
| **Bravecto 112.5 mg spot-on solution Veterinary Dogs -** For very small dogs (2-4.5 kg) | 0.4 | 112.5 |
| **Bravecto 250 mg spot-on solution Veterinary Dogs -** For small dogs (>4.5-10 kg) | 0.89 | 250 |
| **Bravecto 500 mg spot-on solution Veterinary Dogs -** For medium-sized dogs (>10-20 kg) | 1.79 | 500 |
| **Bravecto 1000 mg spot-on solution Veterinary Dogs -** For large dogs (>20-40 kg) | 3.57 | 1,000 |
| **Bravecto 1400 mg spot-on solution Veterinary Dogs -** For very large dogs (>40-56 kg) | 5.0 | 1,400 |

For the full list of excipients, see section 13 – "Additional 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* and *Ctenocephalides canis*) killing activity for 12 weeks,

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

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

The 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.

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:

Commonly observed adverse reactions (1-10 in 100 animals treated) in clinical trials (1.2% of treated dogs) were mild and transient skin reactions at the application site such as erythema or alopecia.
Emesis, lethargy and anorexia have been reported very rarely (less than one animal in 10,000 treated animals) in spontaneous reports after the use of this 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 inform your veterinarian.

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 home page (www.health.gov.il) that directs to the online form for reporting side effects, or by entering the following link:
https://sideeffects.health.gov.il

## 6. TARGET ANIMALS:

Dogs

## 7. ROUTE OF ADMINISTRATION AND DOSAGE:

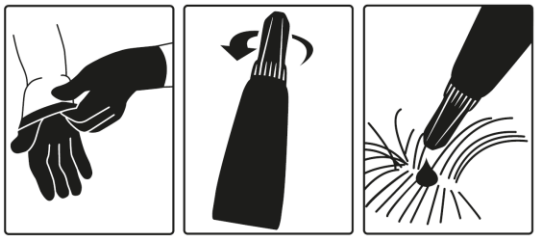
For topical use:
The medicine, Bravecto spot-on should be administered in accordance with the following table (corresponding to a dosage of 25-56 mg fluralaner/kg body weight):

| **Body weight of dog (Kg)** | **Strength and number of pipettes to be administered** | | | | |
|---|---|---|---|---|---|
| | Bravecto 112.5 mg spot-on | Bravecto 250 mg spot-on | Bravecto 500 mg spot-on | Bravecto 1000 mg spot-on | Bravecto 1400 mg spot-on |
| 2-4.5 | I | | | | |
| >4.5-10 | | I | | | |
| >10-20 | | | I | | |
| >20-40 | | | | I | |
| >40-56 | | | | | I |

For dogs above 56 kg body weight, use a combination of two pipettes that most closely matches the body weight of the dog.

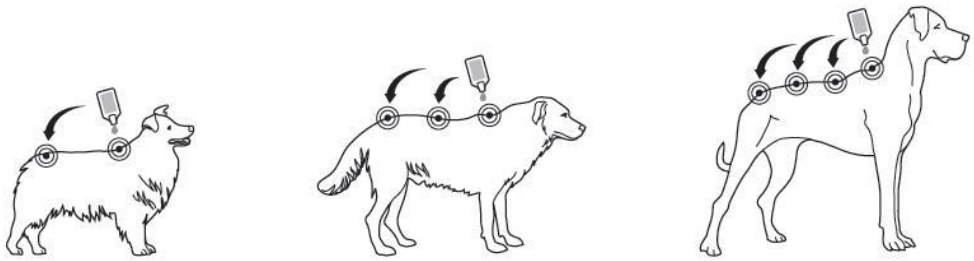
## 8. HOW TO USE THE PRODUCT:

Step 1: Immediately before use, open the sachet and remove the pipette. Put on gloves. The pipette should be held by the base or by the upper rigid portion below the cap in an upright position (tip up) for opening it. The twist-and-use cap should be rotated clockwise or counter clockwise one full turn. The cap will stay on the pipette; it is not possible to remove it. The pipette is open and ready for application when the breaking of the seal is felt.



Step 2: The dog should be standing or lying with its back horizontal during application. Place the pipette tip vertically against the skin between the shoulder blades of the dog.

Step 3: Squeeze the pipette gently and apply the entire contents of the product directly to the dog's skin in one spot (when volume is small) or several spots along the dog's dorsal line, from the shoulder to the base of the tail. Avoid the application of more than 1 ml of solution at any one spot as it could cause some of the solution to run or drip off the dog.



Treatment schedule:
For optimal prevention of flea and tick infestations the product should be administered at intervals of 12 weeks.
For the treatment of *Demodex canis* mite infestations, a single dose of the product should be applied. 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 product should be applied. The need for and frequency of re-treatment should be in accordance with the advice of the prescribing veterinarian.

## 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
  Avoid contact of the product content with the eyes of the animal.
  Do not use directly on skin lesions.
  Do not wash the animal or allow the animal to become immersed in water or swim in water courses within 3 days after treatment.
  In the absence of available data, this medicinal product should not be used on puppies less than 8 weeks old and /or dogs weighing less than 2 kg.
  The product should not be administered at intervals shorter than 8 weeks as the safety at shorter intervals has not been tested.
  For topical use only. This product should not be administered orally.

- Special warnings regarding the safety of the person administering the medicinal product
  Contact with the product should be avoided and disposable protective gloves must be worn when handling the product for the following reasons:
  Hypersensitivity reactions have been reported in a small number of people, which can potentially be serious.
  Persons with a hypersensitivity to fluralaner or to any of the excipients should avoid any exposure to the product.
  The product binds to skin and may also bind to surfaces after spillage of the product. Skin rashes, tingling or numbness have been reported in a small number of individuals after skin contact.
  If skin contact does occur, wash the affected area immediately with soap and water. In some cases, soap and water are not sufficient to remove the product spilled on the fingers.
  Contact with the product may also occur when handling the treated animal. Make sure that your animal's application site is no longer noticeable before resuming contact with the site of application. This includes hugging and cuddling the animal and sharing a bed with the animal. It takes up to 48 hours for the application site to become dry but it will be noticeable for longer.
  If skin reactions occur, consult a physician and show them the product packaging.
  People with a sensitive skin or known allergy in general e.g. to other veterinary medicinal products of this type should handle the veterinary medicinal product as well as treated animals with caution.
  This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.
  This product is harmful after ingestion. Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product. A used pipette should immediately be disposed of. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.
  The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.
  In case of spillage onto, for example table or floor surfaces, remove excess product using paper tissue and clean the area with detergent.

- Pregnancy and lactation
  Can be used in breeding, pregnant and lactating dogs.

- Interactions with other medicinal products and other forms of interactions
  None known

  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 laboratory and clinical field testing, no interactions between Bravecto spot-on solution veterinary for dogs and other routinely used veterinary medicinal products were observed.

- Overdose
  Safety was demonstrated in puppies aged 8-9 weeks and weighing 2.0-3.7 kg treated with overdoses of up to 5 times the maximum recommended dose on three occasions at shorter intervals than recommended (8 weeks).

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

  This veterinary medicinal product was well tolerated in collies with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at 3 times the maximum recommended dose.

- Incompatibility
  None known

## 11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicinal product and any other medicinal products must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning.
- Do not use this medicinal product after the expiry date (Exp. Date) that appears on the packaging. The expiry date refers to the last day of that month.
- Storage conditions:
  Store below 25ºC.
  The pipettes should be kept in the outer packaging to prevent solvent loss or moisture uptake. The sachets should only be opened immediately prior to use.

## 12. INSTRACTIONS 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 throw to sewer.

## 13. ADDITIONAL INFORMATION:

- In addition to the active ingredient(s) the medicinal product also contains:
  Dimethylacetamide
  Glycofurol
  Diethyltoluamide (DEET)
  Acetone

- What the medicine looks like and contents of the package:

Solution for topical use.
Clear colorless to yellow solution
Carton box with pipette made of laminated aluminum/polypropylene foil, closed with an HDPE cap and packed in a laminated aluminum foil sachet.

- Package size:
  Content of 1 or 2 pipettes. Not all sizes may be marketed.

- The product contributes towards the control of environmental flea populations in areas to which treated dogs have access.
  The onset of efficacy is within 8 hours from fleas attachment for fleas (*C. felis*) and 12 hours from ticks attachment for ticks (*I. ricinus*).

- Registration holder name and address:
  Intervet Israel Ltd., Industrial zone Nave Ne'eman, Hod-Hasharon 45240

- Manufacturer name and address:
  Intervet International B.V. (MSD Animal Health)
  Wim de korverstraat 35, 5831 AN Boxmeer, The Netherlands.

- Revised in October 2022 according to MOHs guidelines.

- **Medicinal product registration number at the National Medicines Registry of the Ministry of Health:**
  Bravecto 112.5 mg spot-on solution Veterinary Dogs 160-69-35136-00
  Bravecto 250 mg spot-on solution Veterinary Dogs 160-70-35137-00
  Bravecto 500 mg spot-on solution Veterinary Dogs 160-71-35138-00
  Bravecto 1000 mg spot-on solution Veterinary Dogs 160-72-35139-00
  Bravecto 1400 mg spot-on solution Veterinary Dogs 160-73-35140-00