**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, DOSAGE FORM AND STRENGTH

**Bravecto 112.5 mg Spot-on Solution Veterinary Cats**
**Bravecto 250 mg Spot-on Solution Veterinary Cats**
**Bravecto 500 mg Spot-on Solution Veterinary Cats**

Solution for topical use

## 2. ACTIVE SUBSTANCE

Each 1 ml contains 280 mg Fluralaner.

Each pipette contains:

| Product | Pipette content (ml) | Fluralaner (mg) |
|---|---|---|
| **Bravecto 112.5 mg spot-on solution Veterinary Cats -** For small cats (1.2-2.8 kg) | 0.4 | 112.5 |
| **Bravecto 250 mg spot-on solution Veterinary Cats -** For medium-sized cats (>2.8-6.25 kg) | 0.89 | 250 |
| **Bravecto 500 mg spot-on solution Veterinary Cats -** For large cats (>6.25-12.5 kg) | 1.79 | 500 |

For the full list of excipients and allergens, see section 13 – "Additional information"

## 3. WHAT IS THE MEDICINAL PRODUCT INTENDED FOR

For the treatment of tick and flea infestations in cats.
This veterinary medicinal product is a systemic insecticide and acaricide that provides immediate and persistent flea (*Ctenocephalides felis*) and tick (*Ixodes ricinus*) 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 infestations with ear mites (*Otodectes cynotis*).

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<br>(1 to 10 animals / 100 animals treated): | Skin reactions at the application site (such as Erythema, Itching, Alopecia) # |
| Uncommon<br>(1 to 10 animals / 1,000 animals treated): | Muscle tremor,<br>Apathy, Inappetence, Vomiting,<br>Drooling |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Convulsion |

# mild and transient

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.
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

Cats

## 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 40-94 mg fluralaner/kg body weight):

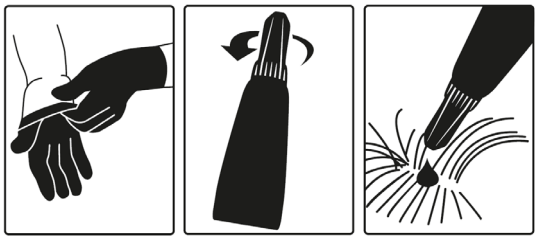
| **Body weight of cat (Kg)** | **Strength and number of pipettes to be administered** | | |
|---|---|---|---|
| | Bravecto 112.5 mg spot-on | Bravecto 250 mg spot-on | Bravecto 500 mg spot-on |
| 1.2-2.8 | I | | |
| >2.8-6.25 | | I | |
| >6.25-12.5 | | | I |

For cats above 12.5 kg body weight, use a combination of two pipettes that most closely matches the body weight of the cat.

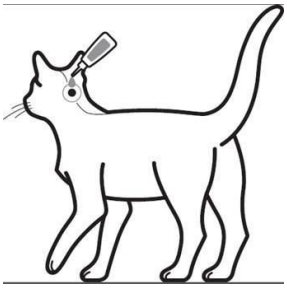
## 8. HOW TO USE THE PRODUCT

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 cat should be standing or lying with its back horizontal for easy application. Place the pipette tip on the base of the skull of the cat.



Step 3: Squeeze the pipette gently and apply the entire contents of the product directly to the cat's skin. The product should be applied on cats up to 6.25 kg body weight in one spot at the base of the skull and in two spots on cats greater than 6.25 kg body weight.

Treatment schedule:
For optimal prevention of flea and tick infestation, the product should be administered at intervals of 12 weeks.
For the treatment of ear mite infestations (*Otodectes cynotis*), a single dose of the product should be applied. A further veterinary examination 28 days after treatment is recommended as some animals may require further treatment with an alternative product.

## 9. WITHDRAWAL PERIOD

Not applicable

## 10. WARNINGS

- Special warnings regarding use of the medicine in the target animal treatment
  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.
  Unnecessary use of antiparasitics or use deviating from the instructions 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.

- 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.
  In the absence of available data, this medicinal product should not be used on kitten less than 9 weeks old and/or cats weighing less than 1.2 kg.
  Do not administer the product 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.
  Do not allow recently treated animals to groom each other.

- 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

  The safety of the medicinal product has not been established in cats during pregnancy and lactation. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

- 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 cats and other routinely used veterinary medicinal products were observed.

- Overdose
  Safety was demonstrated in kitten aged 9-13 weeks and weighing 0.9-1.9 kg treated with overdoses of up to 5 times the maximum recommended dose on three occasions at shorter intervals than recommended (8 weeks).

  Oral uptake of the veterinary medicinal product at the maximum recommended dose was well tolerated in cats, apart from some self-limiting salivation and coughing or vomiting immediately after administration.

- 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 25°C.
  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. 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 throw to sewer. Ask your veterinarian or pharmacist how to dispose of medicines no longer required.
The veterinary medicinal product should not enter water courses as fluralaner may be dangerous for aquatic invertebrates.

## 13. ADDITIONAL INFORMATION

- In addition to the active ingredient 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 pack sizes may be marketed.

- The product contributes towards the control of environmental flea populations in areas to which treated cats have access.
  The onset of efficacy is within 12 hours from fleas attachment for fleas (*C. felis*) and within 48 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 and address**
  Intervet International B.V. (MSD Animal Health)
  Boxmeer, The Netherlands.

- Revised in May 2024 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 Cats 163-17-36245-00
  Bravecto 250 mg spot-on solution Veterinary Cats 163-18-36246-00
  Bravecto 500 mg spot-on solution Veterinary Cats 163-19-36247-00