LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto 1,000 mg spot-on solution for large dogs (>20 – 40 kg)
fluralaner

2. STATEMENT OF ACTIVE SUBSTANCES

1,000 mg fluralaner

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 x 3.57 ml
2 x 3.57 ml

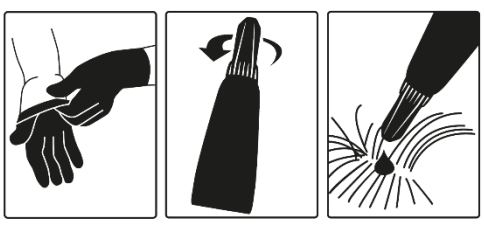
5. TARGET SPECIES

Dogs

6. INDICATIONS

7. METHOD AND ROUTE OF ADMINISTRATION

Spot-on use.
Read the package leaflet before use.
Cap does not come off.



8. WITHDRAWAL PERIOD(S)

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Keep the product in the original packaging until use in order to prevent children from getting access to the product. Avoid contact with skin, mouth and/or eye. Do not contact the application site until it is no longer noticeable.
Wear gloves when handling and administering this product. Read package leaflet for full user safety information.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/5015

17. MANUFACTURER'S BATCH NUMBER

Lot:{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Sachet

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto 1,000 mg spot-on solution for large dogs (>20 – 40 kg)
fluralaner

2. QUANTITY OF THE ACTIVE SUBSTANCE

1,000 mg fluralaner

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3.57 ml

4. ROUTE OF ADMINISTRATION

For spot-on use

1. Put on gloves. 2. Rotate cap (cap cannot be removed). 3. Apply to skin.
Keep the pipette in the sachet until use.

5. WITHDRAWAL PERIOD(S)

Not applicable

6. BATCH NUMBER

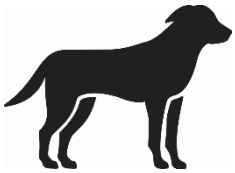
Lot:{number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.



MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1,000 mg fluralaner

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3.57 ml

4. ROUTE(S) OF ADMINISTRATION

For spot-on use.

5. WITHDRAWAL PERIOD(S)

Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bravecto 112.5 mg spot-on solution for very small dogs (2 – 4.5 kg)
Bravecto 250 mg spot-on solution for small dogs (>4.5 – 10 kg)
Bravecto 500 mg spot-on solution for medium-sized dogs (>10 – 20 kg)
Bravecto 1,000 mg spot-on solution for large dogs (>20 – 40 kg)
Bravecto 1,400 mg spot-on solution for very large dogs (>40 – 56 kg)

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet Productions
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto 112.5 mg spot-on solution for very small dogs (2 - 4.5 kg)
Bravecto 250 mg spot-on solution for small dogs (>4.5 – 10 kg)
Bravecto 500 mg spot-on solution for medium-sized dogs (>10 - 20 kg)
Bravecto 1,000 mg spot-on solution for large dogs (>20 – 40 kg)
Bravecto 1,400 mg spot-on solution for very large dogs (>40 – 56 kg)
Fluralaner

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT(S)

Each ml contains 280 mg fluralaner.
Each pipette delivers:

	Pipette content (ml)	Fluralaner (mg)
for very small dogs 2 – 4.5 kg	0.4	112.5
for small dogs >4.5 – 10 kg	0.89	250
for medium-sized dogs >10 – 20 kg	1.79	500
for large dogs >20 – 40 kg	3.57	1,000
for very large dogs >40 – 56 kg	5.0	1,400

Clear colourless to yellow solution.

4. INDICATIONS

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 *C. 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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Mild and transient skin reactions at the application site such as erythema or alopecia were commonly observed in clinical trials (1.2% of treated dogs).
Emesis, lethargy and anorexia have been reported very rarely in spontaneous reports after the use of this product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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

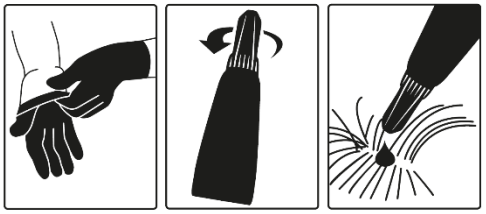
Body weight of dog (kg)	**Strength and number of pipettes to be administered**				
	Bravecto 112.5 mg	Bravecto 250 mg	Bravecto 500 mg	Bravecto 1,000 mg	Bravecto 1,400 mg
2 - 4.5	1				
>4.5 - 10		1			
>10 - 20			1		
>20 - 40				1	
>40 - 56					1

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

9. ADVICE ON CORRECT ADMINISTRATION

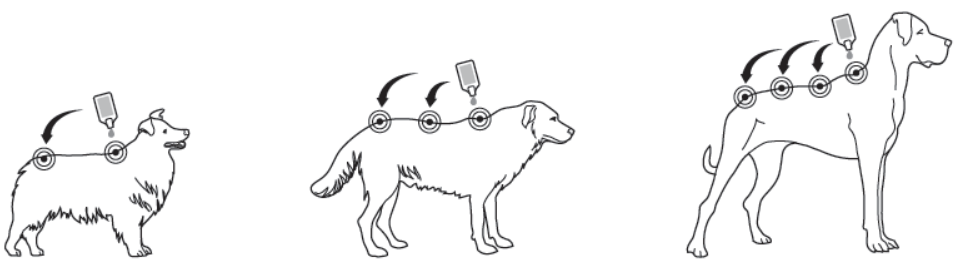
Method of administration

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 directly to the dog's skin in one (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 control of tick and flea infestation, 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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions. 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.

Do not use this veterinary medicinal product after the expiry date stated on the packaging after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:
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 precautions for use in animals:
Care should be taken to avoid contact with the eyes of the animal. Do not use directly on skin lesions.
Do not wash or allow the dog to become immersed in water or swim in water courses within 3 days after treatment.
In the absence of available data, this veterinary 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.
This product is for topical use and should not be administered orally.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Contact with the product should be avoided and disposable protective gloves obtained with this product at the point of sale 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 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, lactation and fertility:
Can be used in breeding, pregnant and lactating dogs.

Interaction with other medicinal products and other forms of interaction:
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 for dogs and 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-week intervals).
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.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

11 June 2021

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

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 for fleas (*C. felis*) and 12 hours for ticks (*I. ricinus*).
Unit dose pipette made of laminated aluminium/polypropylene foil closed with an HDPE cap and packed in a laminated aluminium foil sachet. Each carton box contains 1 or 2 pipettes and a pair of gloves per pipette.
Not all pack sizes may be marketed.

Approved 08 April 2022