LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto 150 mg/ml powder and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each powder vial contains 2.51 g fluralaner.
Each 16 ml solvent vial contains 23.3 mg/ml benzyl alcohol.

3. PACKAGE SIZE

1 vial containing powder, 1 vial containing solvent, 1 vent needle
2 vials containing powder, 2 vials containing solvent, 2 vent needles
5 vials containing powder, 5 vials containing solvent, 5 vent needles
10 vials containing powder, 10 vials containing solvent, 10 vent needles

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

{The following diagrams are printed on the inside of the cardboard box – visible only after opening}

The enclosed vent needle is not intended for product administration.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use the suspension within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

After reconstitution, store below 30 °C. Do not freeze the suspension.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/5091

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for full user safety information.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL OF THE POWDER VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2.51 g fluralaner
Reconstituted suspension for injection: 150 mg/ml fluralaner and 20 mg/ml benzyl alcohol.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

After reconstitution, use within 3 months.
Discard by:

5. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

6. THE WORDS ‘’FOR ANIMAL TREATMENT ONLY’’

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL OF THE SOLVENT VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto solvent

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Contains 23.3 mg/ml benzyl alcohol.

16 ml
Use only 15 ml to reconstitute the suspension. Discard the rest.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

6. THE WORDS ‘’FOR ANIMAL TREATMENT ONLY’’

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Bravecto 150 mg/ml powder and solvent for suspension for injection for dogs

2. Composition

Powder vial:	**Solvent vial:**	**Reconstituted suspension:**
Each vial contains: Active substance: Fluralaner 2.51 g	Each ml contains: Excipients: Benzyl alcohol 22.3 mg	Each ml contains: Active substance: Fluralaner 150 mg Excipients: Benzyl alcohol 20 mg
White to pale yellow powder.	Clear to opaque viscous solution.	Opaque white to pale yellow, slightly viscous suspension.

3. Target species

Dogs.

4. Indications for use

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 months;
- persistent tick killing activity from 3 days to 12 months after treatment for *Ixodes ricinus* and *Dermacentor reticulatus*;
- persistent tick killing activity from 7 days to 12 months after treatment for *Ixodes hexagonus*;
- persistent tick killing activity from 4 days to 12 months after treatment for *Rhipicephalus sanguineus.*

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

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

For reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* from day 3 after treatment for up to 12 months. The effect is indirect due to the veterinary medicinal product's activity against the vector.

For reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* from day 2 after treatment for up to 12 months. The effect is indirect due to the veterinary medicinal product's activity against the vector.

5. Contraindications

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

6. Special warnings

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 (including *Babesia canis canis* and *D. caninum*) cannot be completely excluded.

Unnecessary use of antiparasitics, or use deviating from the instructions given, 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 precautions for safe use in the target species:
Safety of the product has not been assessed in dogs with pre-existing epilepsy. Therefore, use with caution in such dogs based on a benefit/risk assessment by the responsible veterinarian. In the absence of available data, the veterinary medicinal product should not be used on dogs less than 6 months old.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken to avoid accidental self-injection and dermal exposure when administering this veterinary medicinal product.
In case of accidental self-injection, contact a physician and show the label or package leaflet. Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

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.

Overdose:
Following the subcutaneous administration of 3 and 5 times the recommended dose of 15 mg fluralaner/kg body weight every 4 months for a total of 6 doses (days 1, 120, 239, 358, 477 and 596) to 6 months old puppies, the only treatment-related finding was limited to injection site swellings that resolved over time.

The active substance fluralaner was well tolerated in Collies with a deficient multidrug-resistance-protein 1 (MDR1 -/-) following single oral administration at 3 times the maximum recommended dose (168 mg/kg body weight).
Since the peak systemic exposure to fluralaner after subcutaneous administration is not higher compared to oral administration, the subcutaneous injection of the veterinary medicinal product is considered safe in MDR1(-/-) dogs.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Injection site swelling[1]
Uncommon (1 to 10 animals / 1,000 animals treated):
Decreased appetite Tiredness Hyperaemic mucous membranes
Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Muscle tremor, ataxia (incoordination), convulsion

[1]Palpable and/or visual signs of non-inflammatory, non-painful swellings were detected from approximately 2 weeks after injection for a period of 1-2 weeks; swellings self-resolved.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

Subcutaneous use.

Administer 0.1 ml of the reconstituted suspension per kg body weight (equivalent to 15 mg fluralaner per kg body weight) subcutaneously, e.g. between the shoulder blades (dorso-scapular region) of the dog. The dog should be weighed at the time of dosing to calculate an accurate dose.
Underdosing could result in ineffective use and may favour resistance development.

The following table may be used as a dosage guide:

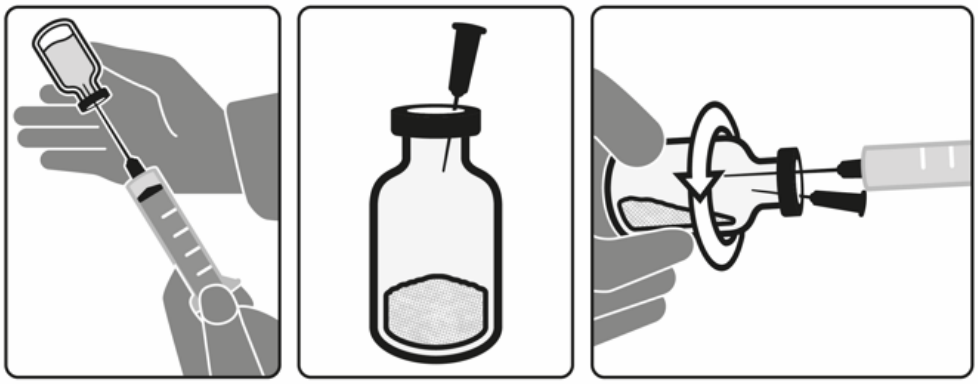
Body weight of the dog (kg)	Dose volume of the reconstituted suspension (ml)
5	0.5
10	1
15	1.5
20	2
25	2.5
30	3
35	3.5
40	4
45	4.5
50	5
55	5.5
60	6

Calculate the dose accordingly for dogs weighing less than 5 kg or more than 60 kg.

9. Advice on correct administration

Reconstitution of the suspension before first use:
Reconstitute 1 vial of powder with 15 ml of solvent. It is recommended to use an 18 G sterile transfer needle and a sterile 20 ml syringe for the reconstitution of the product.

1. Shake the fluralaner powder vial to break up any aggregates prior to reconstitution.
2. Invert the solvent vial at least 3 times until the content is visibly uniform.
3. First inject up to 14 ml of air into the solvent vial, then withdraw **15 ml** of the solvent from the vial (image A). **There is more solvent supplied in the vial than required for reconstitution.** Discard the vial with the rest of the solvent.
4. Insert the 25 G vent needle into the top of the fluralaner powder vial (image B).
5. **While rotating the vial horizontally in your hand,** slowly transfer the 15 ml of solvent into the fluralaner powder vial to ensure complete wetting of the powder (image C).



A B C

6. Once the solvent has been added, remove the vent needle and the transfer needle from the fluralaner powder vial. Discard the needles.
7. Shake the vial vigorously for at least 30 seconds until a thoroughly mixed suspension is formed. The reconstituted product is an opaque white to pale yellow slightly viscous suspension, practically free of aggregates.
8. The expiry date printed on the label of the glass vial refers to the powder as packaged for sale. After reconstitution, the suspension must be discarded within 3 months from the date of reconstitution. Write the discard date on the label of the glass vial.

Method of administration of the reconstituted suspension to the dog:

1. Determine the dose to be administered based on the dog's body weight.
2. Use a sterile syringe and a sterile 18 G needle for administration.
3. The fluralaner powder will separate out of suspension upon standing. Before every use, shake the reconstituted vial vigorously for 30 seconds to achieve a uniform suspension.
4. It may be necessary to inject air into the vial prior to dosing.
5. To maintain a uniform suspension and accurate dosing, the dose should be administered within approximately 5 minutes after drawing it into the dosing syringe.
6. Inject the product subcutaneously, e.g. in the dorso-scapular region.

Do not puncture the stopper of the vial containing the reconstituted suspension more than 20 times. For reconstitution after settling, shake the vial vigorously for at least 30 seconds to achieve a uniform suspension.

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. Treatment with this veterinary medicinal product may begin at any time of the year and can continue without interruption.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product as packaged for sale does not require any special storage conditions.
After reconstitution, store below 30 °C. Do not freeze the suspension.

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.

Shelf life after reconstitution of the suspension according to directions: 3 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
The veterinary medicinal product should not enter water courses as fluralaner may be dangerous for fish and other aquatic organisms.
These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 01708/5091

Each cardboard box contains 1, 2, 5 or 10 powder vial(s) of 2.51 g fluralaner, solvent vial(s) of 16 ml, and sterile vent needle(s).
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]
Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ
Tel: +44 (0)1908 685685

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

17. Other information

POM-V Veterinary medicinal product subject to prescription.

For animal treatment only.

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

I. ricinus and *D. reticulatus* ticks already present on the dog prior to administration of the veterinary medicinal product are killed within 72 hours. *R. sanguineus* ticks already present on the dog prior to administration of the veterinary medicinal product are killed within 96 hours. Newly-infested ticks are killed within 48 hours from one week to 12 months after treatment.

Fleas already present on the dog prior to administration of the veterinary medicinal product are killed within 48 hours. Newly-infested fleas are killed within 24 hours from one week to 12 months after treatment.

Approved: 24 June 2024

Gavin Hall