PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto 250 mg chewable tablets for small dogs (>4.5–10 kg)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Fluralaner
250 mg

3. PACKAGE SIZE

1 chewable tablet
2 chewable tablets
4 chewable tablets

4.. TARGET SPECIES

Dogs

5 INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the blisters in the outer container.

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.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

14. MARKETING AUTHORISATION NUMBER

Vm 01708/5021

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

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

Read the package leaflet before use.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blisters

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

250 mg (>4.5-10 kg)
fluralaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP (mm/yyyy)

5. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

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

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

Each chewable tablet contains:

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

Light to dark brown tablet with a smooth or slightly rough surface and circular shape. Some marbling, speckles or both may be visible.

3 TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

For the treatment of tick and flea infestations on 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 tick killing activity for 12 weeks for *Ixodes ricinus, Dermacentor reticulatus* and *D. variabilis,*
- immediate and persistent tick killing activity for 8 weeks for *Rhipicephalus sanguineus,*
- persistent tick killing activity from 7 days to 12 weeks after treatment for *Ixodes hexagonus.*

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.

For reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for up to 12 weeks. The effect is indirect due to the product's activity against the vector.

For reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for up to 12 weeks. The effect is indirect due to the 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 WARNING(S)

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 th instructions given may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or 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 product.

Special precautions for safe use in the target species:
Use with caution in dogs with pre-existing epilepsy.
In the absence of available data, the 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 for shorter intervals has not been tested.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Keep the product in the original packaging until use, in order to prevent children from getting direct access to the product.
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, lactation and fertility:
The veterinary medicinal product can be used in breeding, pregnant and lactating dogs.

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 Bravecto chewable tablets for dogs and routinely used veterinary medicinal products were observed.

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

Major incompatibilities:
Not applicable.

7. ADVERSE EVENTS

Dogs:

Common (1 to 10 animals / 100 animals treated):	Gastrointestinal effects (Anorexia, Hypersalivation, Diarrhoea, Emesis)*#.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lethargy** Muscle tremor**, Ataxia**, Convulsion**.

* observed in clinical trials
** reported during post marketing safety experience, self-limiting and of short duration
# mild and transient

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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHODS OF ADMINISTRATION

For oral use.

The veterinary medicinal product should be administered in accordance with the following table (corresponding to a dose of 25 – 56 mg fluralaner/kg body weight within one weight band):

Body weight of dog (kg)	**Strength and number of tablets 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 tablets that most closely matches the body weight.

Underdosing could result in ineffective use and may favour resistance development.

9. ADVICE ON CORRECT ADMINISTRATION

The chewable tablets should not be broken or divided.
Administer the veterinary medicinal product at or around the time of feeding.

The chewable tablet is well accepted by most dogs. If the tablet is not taken up voluntarily by the dog it can also be given with food or directly into the mouth. The dog should be observed during administration to confirm that the tablet is swallowed.

Treatment schedule:
For optimal control of flea infestation, the veterinary medicinal product should be administered at intervals of 12 weeks. For optimal control of tick infestation, the timing of retreatment depends on the tick species. See section 4.
For the treatment of *Demodex canis* mite infestations, a single dose of the product should be administered. 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 administered. 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 storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
The veterinary medicinal product should not enter water courses as fluralaner may be dangerous for aquatic invertebrates.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

Joint labelling with central marketing authorisations may include the following wording:
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5016	112.5 mg
Vm 01708/5021	250 mg
Vm 01708/5024	500 mg
Vm 01708/5014	1000 mg
Vm 01708/5019	1400 mg

Cardboard box with containing 1, 2 or 4 chewable tablets.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

May 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

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

Manufacturer responsible for batch release:
Intervet Ges.m.b.H.
Siemensstrasse 107
1210 Vienna
Austria

Contact details to report suspected adverse reactions
MSD Animal Health UK Ltd
Tel.: +44 (0)1908-685685

17. OTHER INFORMATION

The product contributes towards the control of environmental flea populations in areas to which treated dogs have access.
The onset of effect is within 8 hours of attachment for fleas (*C. felis*) and 12 hours of attachment for *I. ricinus* and 48 hours for *D. reticulatus* ticks. The onset of acaricidal efficacy against *I. hexagonus* ticks was demonstrated 7 days after treatment.

For animal treatment only.

POM-V To be supplied only on veterinary prescription.

Approved 24 January 2024