PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto 500 mg chewable tablets for medium-sized dogs (>10 –20 kg)
fluralaner

2. STATEMENT OF ACTIVE SUBSTANCES

Fluralaner 500 mg

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

1 chewable tablet
2 chewable tablets
4 chewable tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD(S)

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

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(S)

Vm 01708/5024

17. MANUFACTURER'S BATCH NUMBER

Lot:{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bravecto 500 mg (>10 –20 kg)
fluralaner

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

3. EXPIRY DATE

EXP: (MM/YYYY)

4. BATCH NUMBER

Lot: {number}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET:
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)

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 GesmbH
Siemensstrasse 107
1210 Vienna
Austria

2. 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)

fluralaner

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each chewable tablet of Bravecto 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.

4. INDICATIONS

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. ADVERSE REACTIONS

Mild and transient gastrointestinal effects such as diarrhoea, vomiting, inappetence, and drooling were commonly observed in clinical trials (1.6% of treated dogs).

Lethargy, muscle tremor, ataxia and convulsions have been reported very rarely in spontaneous reports.

Most reported adverse reactions were self-limiting and of short duration.

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 that 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 oral use.

Bravecto chewable tablets 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

Bravecto is a chewable tablet and 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 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 (including *Babesia canis canis* and *D. caninum*) cannot be completely excluded.

Special precautions for use in animals:
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 (symptoms, emergency procedures, antidotes):
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:
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

18/07/2022.

Detailed information on this veterinary medicinal product is available on the website of the European Medicine 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 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.

Cardboard box with 1 aluminium foil blister sealed with PET aluminium foil lid stock containing 1, 2 or 4 chewable tablets.
Not all pack sizes may be marketed.

Approved 18 November 2022