



PACKAGE LEAFLET FOR:

EN Bravecto™ chewable tablets for dogs

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 1000 mg chewable tablets for large dogs (>20 – 40 kg)
Bravecto 1400 mg chewable tablets for very large dogs (>40 – 56 kg)

Fluralaner

STATEMENT OF THE ACTIVE SUBSTANCE

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	1000
for very large dogs >40 – 56 kg	1400

INDICATIONS

For the control of tick and flea infestations on dogs for 12 weeks. This veterinary medicinal product is a systemic insecticide and acaricide with a long duration of action that provides immediate and persistent tick (adult and juvenile *Ixodes ricinus*, *Ixodes hexagonus*, *Ixodes scapularis*, *Ixodes holocyclus*, *Dermacentor reticulatus*, *Dermacentor variabilis* and *Rhipicephalus sanguineus*) and flea (*Ctenocephalides felis* and *Ctenocephalides canis*) 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 onset of effect is within 8 hours of attachment for fleas (*C. felis*) and 12 hours of attachment for ticks (*I. ricinus*).

The product effectively controls environmental flea populations in areas to which treated dogs have access.

The product can be used as part of a treatment strategy for flea allergy dermatitis.

CONTRAINDICATIONS

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

ADVERSE REACTIONS

Singular cases (1.6%) of mild and transient gastrointestinal symptoms such as diarrhoea/ vomiting/ inappetence/ drooling related to the route of administration of the product were observed in clinical studies.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

TARGET SPECIES

Dogs

DOSAGE FOR EACH SPECIES, ROUTE(S) 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):

Bodyweight (kg) of dog	Number and strength of tablet to be administered				
	Bravecto 112.5 mg	Bravecto 250 mg	Bravecto 500 mg	Bravecto 1000 mg	Bravecto 1400 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.

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 tick and flea infestation, the veterinary medicinal product should be administered at intervals of 12 weeks. The product may be administered year round.

WITHDRAWAL PERIOD

Not applicable

SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

Keep out of the sight and reach of children.

Do not use after the expiry date stated on the blister. The expiry date refers to the last day of that month.

SPECIAL WARNINGS

Special warnings for each target species:

The risk of transmission of parasite borne diseases is substantially reduced due to the rapid onset of acaricidal and insecticidal action. 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 if conditions are unfavourable.

Special precautions for use in animals

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.

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 product 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 drugs such as non-steroidal anti-inflammatory drugs (NSAIDs) and the cumarin 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 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.

Incompatibilities:

None known.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

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.

OTHER INFORMATION

Carton box with 1 aluminium foil blister sealed with laminated aluminium foil lid stock containing 1, 2 or 4 chewable tablets.

Not all pack sizes may be marketed.

For animal treatment only.

Product of Intervet International B.V., Boxmeer, The Netherlands