FLURALANER 112.5 MG/250 MG/500 MG/ 1000 MG/1400 MG CHEWABLE TABLETS

BRAVECTO®

Fluralaner 112.5 mg chewable tablets for very small dogs
Fluralaner 250 mg chewable tablets for small dogs
Fluralaner 500 mg chewable tablets for medium-sized dogs
Fluralaner 1000 mg chewable tablets for large dogs
Fluralaner 1400 mg chewable tablets for very large dogs

NOT FOR HUMAN USE FOR ANIMAL TREATMENT ONLY

WARNING: To be sold by the retail on the prescription of a "Veterinary Doctor" only.

Statement of active Substance:
Composition of the formulation:

Each chewable tablet contains: Fluralaner 112.5 mg /250 mg /500 mg/1000 mg/ 1400 mg

The table below shows the five tablet strengths and the dog body weight ranges.

Chewable tablet weight (g)	Strength fluralaner (mg/tablet)	Dog body weight range (kg)
0.82	112.5	2-4.5
1.83	250	>4.5-10
3.67	500	>10-20
7.33	1000	>20-40
10.26	1400	>40-56

Pharmaceutical form:
Chewable tablet.
Ectoparasiticides for systemic use.

355454 R1

Indication (s):
For the treatment of tick and flea infestations on dogs for 3 months. 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 3 months.

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 provides protection against transmission of *Babesia canis* by *Dermacentor reticulatus* ticks by killing the ticks before disease transmission occurs. This has been shown over a 3 months period after treatment.

The product effectively controls environmental flea populations in areas to which treated dogs have access.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* spp. mites. In a controlled trial, treatment with fluralaner resulted in the complete removal of *Demodex* spp. mites from treated dogs.

For the treatment of *Sarcoptic* mange and *Otodectes spp.* mite infestations.

Contraindications:
Do not use in case of hypersensitivity to the active substances or to any of the excipients.

Adverse reactions:
Singular cases (1.6%) of mild and transient gastrointestinal symptoms such as diarrhea/vomiting/in appetence/drooling related to the root of administration of the product were observed in clinical studies.

Lethargy, muscle tremor, ataxia and convulsion have been reported very rarely in spontaneous reports. Most reported adverse reactions were self-limiting and of short duration.

Target Species
Dogs.

Amount to be administered and administration route:
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 (kg)/dog	Number & strength of tablet to be administered				
	Bravecto 112.5mg	Bravecto 250mg	Bravecto 500mg	Bravecto 1000mg	Bravecto 1400mg
2-4.5	1				
>4.5-10		1			
>10-20			1		
>20-40				1	
>40-56					1

The chewable tablet should not be broken or divided. For dogs above 56 kg body weight, use combination of two tablets that most closely matches the body weight.

Method of administration:
Administer the Bravecto chewable tablet 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 the interval of 3 months. For optimal control of tick infestation, the timing of retreatment depends on the tick species.-Please refer indications. Bravecto may be administrated year around.

For the treatment of mite infestations, 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.

Overdose:
No adverse reactions were observed following oral administration to puppies aged 8-9 weeks and weighing 2.0-3.6 kg treated with overdoses of up to 5 times the maximum recommended dose (56 mg, 168 mg and 280 mg fluralaner/kg body weight) on three occasions at shorter intervals than recommended (8-week intervals)..

There were no findings on reproductive performance and no findings of concern on offspring viability when fluralaner was administered orally to Beagle dogs at overdoses of up to 3 times the maximum recommended dose (up to 168 mg/kg of fluralaner).

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 (168 mg/kg BW). No treatment-related clinical signs were observed.

Special warning(s):
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:
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.

Use during pregnancy and lactation:
The safety of the veterinary medicinal product in breeding, pregnant and lactating dogs has been demonstrated. Can be used in breeding, pregnant and lactating dogs.

Pharmacodynamics properties:
Pharmacotherapeutic group: Ectoparasiticides for systemic use
ATCvet code: QP53BX05
Fluralaner is an acaricide and insecticide. It is efficacious against ticks (*Ixodes spp., Dermacentor spp.* and *Rhipicephalus sanguineus*) and fleas (*Ctenocephalides spp.*) and mites (Demodex spp., Sarcoptes spp., Otodectes spp.) on the dog
Fluralaner has a high potency against ticks and fleas by exposure via feeding, i.e. it is systemically active on target parasites.
Fluralaner is a potent inhibitor of parts of the arthropod nervous system by acting antagonistically on ligand-gated chloride channels (GABA-receptor and glutamate-receptor).
In molecular *on-target* studies on insect GABA receptors of flea and fly, fluralaner is not affected by dieldrin resistance.

In *in-vitro bio-assays*, fluralaner is not affected by proven field resistances against amidines (tick), organophosphates (tick, mite), cyclodienes (tick, flea, fly), macrocyclic lactones (sea lice), phenylpyrazoles (tick, flea), benzophenyl ureas (tick), pyrethroids (tick, mite) and carbamates (tick, mite).
Newly emerged fleas on a dog are killed before viable eggs are produced. An *in-vitro* study also demonstrated that very low concentrations of fluralaner stop the production of viable eggs by fleas. The flea life cycle is broken due to the rapid onset of action and long lasting efficacy against adult fleas on the animal and the absence of viable egg production.

Pharmacokinectics particulars:
Following oral administration, fluralaner is readily absorbed reaching maximum plasma concentrations within 1 day. Food enhances the absorption. Fluralaner is systemically distributed and reaches the highest concentrations in fat, followed by liver, kidney and muscle. The prolonged persistence and slow elimination from plasma (t1/2 = 12 days) and the lack of extensive metabolism provide effective concentrations of fluralaner for the duration of the inter-dosing interval. Individual variation in Cmax and t1/2 was observed. The major route of elimination is the excretion of unchanged fluralaner in faeces (~90% of the dose). Renal clearance is the minor route of elimination.

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.

Incompitabilities:
None Known

Special Precautions for the disposal of unused veterinary medicinal product or wastematerials derived from the use of such product:
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Withdrawal period(s):
Not applicable.

Storage:
Do not store above 30°C
Keep out of sight and reach of Children

Shelf life:
Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Nature and composition of immediate packaging:
Carton box with 1 aluminium foil blister sealed with laminated aluminium foil lid stock containing 1, 2 or 4 chewable tablets.

Manufactured by:
Intervet GesmbH
Siemensstrasse 107
1210, Vienna
Austria.

Imported and Marketed by:
Intervet India Pvt. Ltd.,
Sagar Complex, Bldg. B-1, Gala No. 12 to 16,
Ovali Village, Bhiwandi,
Maharashtara, Tal: Bhiwandi -16, (Thane Z5)

MSD Animal Health

PSC020A15 01 R2 608x304mm Black x=10mm y=15mm 103
Moved to repository by COPPUS 23:Nov:2021 15:21

PSC020A15 01 R2 608x304mm Black x=10mm y=15mm 103
Moved to repository by COPPUS 23:Nov:2021 15:21