

Fluralaner 112.5 mg and Moxidectin 5.6 mg spot-on solution for small Cats

Fluralaner 250 mg and Moxidectin 12.5 mg spot-on solution for medium sized Cats

Fluralaner 500 mg and Moxidectin 25 mg spot-on solution for large Cats

BRAVECTO
PLUS



NOT FOR HUMAN USE FOR ANIMAL TREATMENT ONLY

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

Composition of the formulation:

Ingredients	Composition per size		
	Small cats	Medium sized cats	Large cats
Fluralaner non-micronized or micronized	112.5mg	250mg	500mg
Moxidectin	5.6mg	12.5mg	25.0mg

Pack Size:

Body weight range (kg)	Fluralaner dose (mg per pipette)	Moxidectin dose (mg per pipette)	Volume (rounded, ml per pipette)
1.2 – 2.8 kg	112.5	5.6	0.4
>2.8 – 6.25 kg	250	12.5	0.89
>6.25 – 12.5 kg	500	25	1.79

Pharmaceutical Form: Spot-on solution. Clear colourless to yellow solution.

Target species: Cats

Indications for use, specifying each target species:

For cats with, or at risk from, mixed parasitic infestations by ticks and fleas, gastrointestinal nematodes (4th stage larvae, immature adults and adults of *Toxocara cati* and *Ancylostoma tubaeforme*) or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks or fleas and one or more of the other target parasites is indicated at the same time.

For the treatment of tick and flea infestations in cats providing immediate and persistent flea (*Ctenocephalides felis*) and tick (*Ixodes ricinus*, *Ixodes scapularis*, *Rhipicephalus sanguineus*, *Haemaphysalis longicornis*) 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.

For the treatment of Otodectes cynotis infestations.

For the prevention of heartworm disease caused by *Dirofilaria immitis* for 12 weeks.

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

Contraindications:

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

Special warnings for each target species

Ticks and fleas 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.

Cats in areas endemic for heartworm (or those which have travelled to endemic areas) may be infected with adult heartworms. No therapeutic effect against adult *Dirofilaria immitis* has been established. It is therefore recommended, in accordance with good veterinary practice, that all animals 6 months of age or more, living in areas where a vector exists should be tested for existing adult heartworm infections before beginning preventive use with the veterinary medicinal product.

To ensure continuous prevention of heartworm disease, a repetition of treatment is necessary at 12-week intervals. At the time of treatment Bravecto Plus is effective against *D. immitis* larvae (L3 and L4), which have developed in the previous 30 days and against incoming *D. immitis* larvae (L3 and L4) for the subsequent 60 days.

Prevention of heartworm disease in cats that are only temporarily in endemic areas should start at the latest within 1 month after the first expected exposure to mosquitoes and should be continued at 12-week intervals until return to a non-endemic area.

For the treatment of infections with the gastrointestinal nematodes *T. cati* and *A. tubaeforme*, the need for, and the frequency of, re-treatment as well as the choice of the treatment (monosubstance or combination product) should be evaluated by the prescribing veterinarian.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class under specific circumstances. The use of this veterinary medicinal product should be based on the assessment of each individual case and on local epidemiological information about the current susceptibility of the target species in order to limit the possibility of a future selection for resistance. Parasite control is recommended throughout the period of potential infestation risk. Avoid frequent swimming or shampooing the animal because the maintenance of effectiveness of the product in these cases has not been tested.

Special precautions for use

Special precautions for use in animals

Care should be taken to avoid contact with the eyes of the animal. Do not use directly on skin lesions.

In the absence of available data, treatment of kittens less than 9 weeks of age and cats less than 1.2 kg bodyweight is not recommended.

Treatment of male breeding animals is not recommended.

The product should not be administered at intervals shorter than 8 weeks as the safety at shorter intervals has not been tested. This product is for topical use and should not be administered orally.

Oral uptake of the product at the maximum recommended dose of 93 mg fluralaner + 4.65 mg moxidectin/kg body weight induced some self-limiting salivation or single incidences of vomiting immediately after administration.

It is important to apply the dose as indicated to prevent the animal from licking and ingesting the product.

Do not allow recently treated animals to groom each other.

Do not allow treated animals to come into contact with untreated animals until the application site is dry.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product is harmful after ingestion. Keep the product in the sachet until use, in order to prevent children from getting direct access to the product. A used pipette should immediately be disposed of. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

This product and the wet skin of a recently treated animal may be slightly irritating to skin and moderately irritating to eyes. Avoid contact with skin, mouth and/or eye, including hand-to-mouth and/or hand-to-eye contact. Do not eat, drink or smoke while handling the product. Do not contact, or allow children to contact the application site until it is dry; it is therefore recommended to treat the animal in the evening. On the day of treatment, treated animals should not be permitted to sleep in the same bed as their owner, especially children.

Wash hands thoroughly with soap and water immediately after use of the product. If skin contact does occur, wash the affected area immediately with water. In some cases, water is not sufficient to remove the product spilled on the fingers. If a sticky residue persists on the skin after washing with water, then this can be removed using household items containing organic solvents [e.g., rubbing alcohol (ethanol), isopropyl alcohol] or nail polish remover (acetone)] applied gently with a swab.

In case of contact with the eyes, immediately rinse thoroughly with water.

The product is highly flammable. Keep away from heat, sparks, open flame or other sources of ignition.

Adverse reactions (frequency and seriousness)

Mild and transient skin reactions at the application site (alopecia, flaking skin and pruritus) were observed in clinical trials (2.9% of treated cats).

The following other adverse reactions were observed in clinical trials shortly after administration: dyspnoea after licking the application site, hematemesis, diarrhea, lethargy, hypersalivation,

pyrexia, tachypnoea, mydriasis (0.1% of treated cats).

Based on post-registration experience decreased appetite, tremors and ataxia have been reported very rarely (less than 1 animal in 10,000 animals treated).

Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in pregnant or lactating animals and therefore use in such animals is not recommended.

Interaction with other medicinal products and other forms of interaction

Macrocyclic lactones including moxidectin have been shown to be substrates for p-glycoprotein. Therefore, during treatment with Bravecto Plus, other products that can inhibit p-glycoprotein (e.g. cyclosporine, ketoconazole, spinosad, verapamil) should only be used concomitantly according to the benefit-risk assessment of the responsible veterinarian. The safety of concurrent use of Bravecto Plus and praziquantel (at a dose of 16.7 mg /kg bodyweight) has been confirmed.

Amounts to be administered and administration route

For spot-on use.

Bravecto Plus spot-on solution is available in three pipette sizes. The following table defines the size of pipette to be used according to the body weight of the cat (corresponding to a dose of 40-94 mg fluralaner/kg body weight and 2-4.7 moxidectin/kg body weight):

Weight of cat (kg)	Pipette size to be used
1.2 – 2.8	Bravecto Plus 112.5 mg + 5.6 mg spot-on solution for small cats
>2.8 – 6.25	Bravecto Plus 250 mg + 12.5 mg spot-on solution for medium-sized cats
>6.25 – 12.5	Bravecto Plus 500 mg + 25 mg spot-on solution for large cats

Within each weight band, the content of one whole pipette should be used.

For cats more than 12.5 kg, use a combination of two pipettes that most closely matches the body weight.

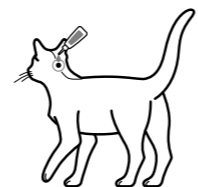
Method of administration:

Step 1: Immediately before use, open the sachet and remove the pipette. The pipette should be held by the base or by the upper rigid portion below the cap in an upright position (tip up) for opening it. The twist-and-use cap should be rotated clockwise or counter clockwise one full turn. **The cap will stay on the pipette; it is not possible to remove it.** The pipette is open and ready for application when the breaking of the seal is felt.



Step 2: The cat should be standing or lying with its back horizontal for easy application. Place the pipette tip on the base of the skull of the cat.

Step 3: Squeeze the pipette gently and apply the entire contents directly to the cat's skin. The product should be applied on cats up to 6.25 kg body weight in one spot at the base of the skull and in two spots at the base of the skull on cats greater than 6.25 kg bodyweight.



Treatment schedule:

For optimal control of tick and flea infestation and for prevention of heartworm disease, the product should be administered at intervals of 12 weeks.

Kittens below six months of age should be weighed regularly. Treatment should be appropriately adapted by the veterinarian to suit the individual weight changes. From six months of age, cats should be treated at 12-week intervals.

Cats in areas endemic for heartworm, or cats which have travelled to endemic areas, may be infected with adult heartworms. Therefore prior to application of Bravecto Plus for the concurrent prevention of infection with adult *D. immitis*, the advice provided in section 4.4 should be considered.

For the concurrent treatment of infections with the gastrointestinal nematodes *T. cati* and *A. tubaeforme*, 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 and take into account the local epidemiological situation.

Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions were observed following topical administration to kittens aged 9-13 weeks and weighing 0.9-1.9 kg treated with overdoses of up to 5 times the maximum recommended dose (93 mg fluralaner + 4.65 mg moxidectin, 279 mg fluralaner + 13.95 mg moxidectin and 465 mg fluralaner + 23.25 mg moxidectin/kg body weight) on three occasions at shorter intervals than recommended (8-week intervals).

Withdrawal period(s)

Not applicable.

List of excipients

Butylhydroxytoluene
Dimethylacetamide
Glycolulol
Diethyltoluamide
Acetone

Incompatibilities

None known.

Shelf life

Shelf life of the veterinary medicinal product: 24 months

Special precautions for storage

Do not store above 30°C.

The pipettes should be kept in the sachets to prevent solvent loss or moisture uptake. The sachets should only be opened immediately prior to use.

Nature and composition of immediate packaging

Unit dose pipette made of laminated aluminium/polypropylene foil closed with a high-density polyethylene (HDPE) cap and packed in a laminated aluminium foil sachet.

Each cardboard box contains 1 or 2 pipettes.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Do not allow the product to enter water courses as this may be dangerous for fish and other aquatic organisms.

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Imported and marketed by:

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