



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/783442/2013  
EMA/V/C/002526

## Bravecto (*fluralaner*)

An overview of Bravecto and why it is authorised in the EU

### What is Bravecto and what is it used for?

Bravecto is a veterinary medicine used to treat parasitic infestations in dogs and cats. It may be used:

- to treat flea and tick infestations in dogs and cats;
- as part of the management of flea allergy dermatitis (an allergic reaction to flea bites) in dogs and cats;
- to treat demodectic and sarcoptic mange (skin infestation caused by two different mites) in dogs;
- to reduce the risk of infection with the parasite *Babesia canis canis* transmitted by *Dermacentor reticulatus* ticks in dogs;
- to treat ear mite infestations in cats.

Bravecto contains the active substance fluralaner.

### How is Bravecto used?

Bravecto is available as a spot-on solution in a pipette for use on dogs and cats and as chewable tablets for use in dogs. The spot-on solution and tablets are available in different strengths for dogs and cats of different weights.

The content of one full Bravecto pipette is applied to the dog or cat's skin between the shoulder blades of the dog and at the base of the skull of the cat. For dogs, several spots may be applied from the initial spot in a line to the base of the tail. The pipette to use is selected on the basis of the dog or cat's weight. After being given, its actions last for 12 weeks against fleas and ticks. Treatment should be repeated every 12 weeks for optimal flea and tick control.

Bravecto tablets are given at or around the dog's feeding time as a tablet of the appropriate strength for the dog's bodyweight. After being given, its actions last for 12 weeks against fleas and 8 to 12 weeks against ticks. Treatment should be repeated every twelve weeks for optimal flea control. For optimal tick control, treatment should be repeated every 8 to 12 weeks depending on the tick species.

A single treatment is required for demodectic and sarcoptic mange in dogs and ear mites in cats. As demodectic mange is caused by a number of factors, it is advisable for any underlying disease to be treated. The need for and frequency of re-treatment for sarcoptic mange should follow veterinary

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

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advice. For ear mite infestations, a veterinary check is advised 28 days after treatment. The veterinarian will decide if additional treatment is needed.

To reduce the risk of infection with *B. canis canis* in dogs, Bravecto chewable tablets should be given every 12 weeks.

Bravecto can only be obtained with a prescription.

For more information about using Bravecto, see the package leaflet or contact your veterinarian or pharmacist.

## **How does Bravecto work?**

The active substance in Bravecto, fluralaner, acts as an 'ectoparasiticide'. This means that it kills parasites that live on or in the skin or in the fur or ears of animals, such as fleas, ticks and mites. By killing *D. reticulatus* ticks, Bravecto also reduces the risk of infection with *B. canis canis*. In order to be exposed to the active substance, parasites must attach to the skin and commence feeding on the dog or cat.

Fluralaner kills fleas, ticks and mites that have ingested the dog's or cat's blood by acting on their nervous system. It blocks the normal movement of charged chloride particles (ions) in and out of nerve cells, especially those associated with gamma-aminobutyric acid (GABA) and glutamate, two substances that convey messages between nerves (neurotransmitters). This results in uncontrolled activity of the nervous system and the paralysis and death of the parasites. Fluralaner kills fleas before they can lay eggs and so helps to reduce contamination of the dogs' or cats' environment.

Bravecto kills fleas within 8 hours and ticks within 12-48 hours in dogs. In cats, Bravecto kills fleas within 12 hours and ticks within 48 hours.

## **What benefits of Bravecto have been shown in studies?**

The effectiveness of Bravecto against fleas and ticks was investigated in both laboratory and field studies.

In an EU field study involving 561 dogs with flea and/or tick infestations, the effects of Bravecto tablets were compared with those of another product, fipronil, that kills fleas and ticks, applied as a spot-on solution to the skin of the dogs. The main measure of effectiveness was the reduction in the number of fleas and ticks in the infested dogs during the 3 months after receiving treatment. The field study showed that Bravecto was effective in reducing the number of fleas and ticks in dogs with existing flea or tick infestations and that its effects against fleas and most tick species persisted for 3 months.

Two further EU field studies involved dogs and cats with flea and/or tick infestations and compared the effects of Bravecto spot-on solution with fipronil spot-on solution. Bravecto was effective against fleas and ticks for up to 12 weeks after treatment, and was as effective as fipronil in terms of the percentage of dogs and cats as well as households free of fleas and ticks.

A study conducted in Europe looked at the effectiveness of Bravecto chewable tablets and Bravecto spot-on solution in dogs with demodectic mange. Effectiveness was 95% and 94% for Bravecto chewable tablets and Bravecto spot-on solution respectively based on the percentage of dogs free from live mites at days 56 and 84 after treatment.

A study conducted in Europe involved dogs with sarcoptic mange and compared Bravecto chewable tablets and Bravecto spot-on solution to another medicine authorised to treat sarcoptic mange. Bravecto and the comparator medicine were both 100% effective as all treated dogs were free from live mites when skin scrapings were taken on days 56 and 84 after treatment.

One laboratory study and one field study conducted in Europe showed that Bravecto chewable tablets were 100% effective in preventing the transmission of *B. canis canis* by *D. reticulatus* for up to 12 weeks in dogs.

In a study conducted in the EU involving cats with ear mites, the effectiveness of Bravecto was more than 90% based on presence of live ear mites at day 28 after treatment.

## **What are the risks associated with Bravecto?**

The most common side effects of the tablets in dogs (which may affect more than 1 in 100 animals) are mild and short-lived diarrhoea, vomiting, lack of appetite and drooling.

The most common side effect of the spot-on solution (which may affect more than 1 in 100 animals) is a mild short-lived skin reaction at the application site, such as erythema (redness) and pruritus (itching) or hair loss.

Because parasites must start feeding on the dog or cat in order to be killed by the medicine, they might still be able to transmit any diseases with which they may be infected.

For the full list of side effects reported with Bravecto, see the package leaflet.

## **What are the precautions for the person who gives the medicine or comes into contact with the animal?**

### **Bravecto chewable tablets**

The medicine should be kept in the original package until use, in order to prevent children directly accessing the medicine.

Hypersensitivity ('allergic') reactions to the medicine have been reported in humans.

People handling the medicine should not smoke, eat or drink and should wash their hands thoroughly with soap and water immediately after handling the product.

### **Bravecto spot-on solution**

Contact with the medicine should be avoided. Disposable protective gloves obtained with the medicine must be worn when handling the medicine. This is because potentially serious hypersensitivity ('allergic') reactions have been reported in a small number of people.

People with hypersensitivity to fluralaner or to any of the other ingredients should avoid any contact with the medicine.

The medicine binds to skin and may also bind to surfaces after spillage of the medicine. Skin rashes, tingling or numbness have been reported in a small number of individuals after skin contact. If skin contact occurs, the affected area must be washed immediately with soap and water. In some cases, soap and water are insufficient to remove medicine spilled on fingers.

Contact with the medicine may also occur when handling the treated animal. Contact with the application site should be avoided until it is no longer noticeable. This includes cuddling the animal and sharing a bed with the animal. It takes up to 48 hours for the application site to become dry but it will be noticeable for longer.

If skin reactions occur, medical advice should be sought and the package leaflet or label shown to the doctor.

People with a sensitive skin or known allergies (e.g. to other veterinary medicines of this type) should handle the medicine as well as treated animals with caution.

This medicine can cause eye irritation. In case of eye contact, the eyes should be rinsed immediately and thoroughly with water.

This medicine is harmful if swallowed. The medicine should be kept in the original package until use, in order to prevent children directly accessing the medicine. Used pipettes should be disposed of immediately. In case of accidental ingestion, medical advice should be sought and the package leaflet or label shown to the doctor.

Bravecto spot-on solution should be kept away from heat, sparks, open flames or other fire sources since it is highly flammable. In case of spillage on table or floor surfaces, excess medicine should be removed using paper tissue and the area cleaned with detergent.

### **Why is Bravecto authorised in the EU?**

The European Medicines Agency decided that Bravecto's benefits are greater than its risks and it can be authorised for use in the EU.

### **Other information about Bravecto**

Bravecto received a marketing authorisation valid throughout the EU on 11 February 2014.

Further information on Bravecto can be found on the Agency's website:  
[ema.europa.eu/medicines/veterinary/EPAR/bravecto](http://ema.europa.eu/medicines/veterinary/EPAR/bravecto).

This overview was last updated in 12-2021.