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EPAR summary for the public

Bravecto

fluralaner

This is a summary of the European public assessment report (EPAR) for Bravecto. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Bravecto.

For practical information about using Bravecto animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Bravecto and what is it used for?

Bravecto is a veterinary medicine used to treat flea and tick infestations in dogs and cats. It may be used as part of the management of flea allergy dermatitis (an allergic reaction to flea bites). 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 twelve weeks for optimal flea and tick control.

Bravecto tablets are given 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.

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



Bravecto can only be obtained with a prescription.

How does Bravecto work?

The active substance in Bravecto, fluralaner, acts as an 'ectoparasiticide'. This means that it kills parasites that live on the skin or in the fur of animals, such as fleas and ticks. In order to be exposed to the active substance, fleas and ticks must attach to the skin and commence feeding on the dog or cat.

Fluralaner kills fleas and ticks 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 fleas and ticks. Fluralaner kills fleas before they can lay eggs and so helps to reduce contamination of the dogs' or cats' environment.

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.

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 fleas and ticks must start feeding on the dog 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 all 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?

This product is harmful if swallowed. The product should be kept in the original package until use, in order to prevent children directly accessing the medicine. Suitable gloves should be worn when

handling or giving Bravecto spot-on solution to dogs and cats. In case of spillage on table or floor surfaces, excess Bravecto spot-on solution should be removed using paper tissue and the area cleaned with a detergent.

People handling the medicine should not smoke, eat or drink and should wash their hands thoroughly after handling the product. Used pipettes should be disposed of immediately. If the product is accidentally swallowed by a person, the advice of a doctor should be sought immediately and the package leaflet or label shown to the doctor.

Bravecto spot-on solution and the wet skin of a recently treated animal may be slightly irritating to skin and/or eyes. Contact with skin and/or eyes should be avoided including hand to eye contact. Contact with the application site should be avoided until it is dry so it is recommended to apply to the animal in the evening. On the day of applying Bravecto spot-on solution treated animals should not be allowed to sleep in the same bed as their owner, especially children. In case of eye contact the affected area should be rinsed immediately with water.

Bravecto spot-on solution should be kept away from heat, sparks, open flames or other fire sources as it is highly flammable.

Why is Bravecto approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Bravecto's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Bravecto:

The European Commission granted a marketing authorisation valid throughout the EU for Bravecto on 11 February 2014.

The full EPAR for Bravecto can be found on the Agency's website: ema.europa.eu/Find/medicine/Veterinary_medicines/European_public_assessment_reports. For more information about treatment with Bravecto, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2016.