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SCIENCE MEDICINES HEALTH

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Bravecto Plus (*fluralaner / moxidectin*)

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

What is Bravecto Plus and what is it used for?

Bravecto Plus is a veterinary medicine used in cats to treat mixed infestations with both ticks or fleas and ear mites and/or worms that live inside the body. The medicine can be used:

- to treat tick infestations
- to treat flea infestations. It can also be used as part of a treatment for flea allergy dermatitis (an allergic reaction to flea bites)
- to treat ear mite infestations
- to treat roundworms and hookworms in the gut
- to prevent heartworm disease

Bravecto Plus must only be used when there is a need to treat ticks or fleas and one or more of the parasites listed above. Bravecto Plus contains the active substances fluralaner and moxidectin.

How is Bravecto Plus used?

Bravecto Plus is available as a spot-on solution in a pipette. The spot-on solution is available in different strengths for cats of different weights.

The content of one full Bravecto Plus pipette is applied to the cat's skin at the base of the skull. The pipette to use is selected on the basis of the cat's weight. Bravecto Plus kills fleas and ticks within 48 hours. The medicine's actions against fleas and ticks last for 12 weeks after being applied. Where necessary, treatment can be repeated every twelve weeks. For ear mite infestations, a veterinary check is necessary 28 days after treatment. The veterinarian will decide if additional treatment is needed.

When given repeatedly at 12-week intervals, Bravecto Plus is effective at continuously preventing heartworm disease.

The medicine can only be obtained with a prescription.

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

How does Bravecto Plus work?

The active substances in Bravecto Plus, fluralaner and moxidectin, work in different ways to kill parasites. In order to be exposed to the active substance fluralaner, fleas and ticks must commence feeding on the cat.

Fluralaner acts as an 'ectoparasiticide'. This means that it kills parasites present on the skin or in the fur or ears of animals, such as fleas, ticks and ear mites. Fluralaner kills fleas and ticks that have ingested the cat's blood by causing uncontrolled activity of their nervous system. This results in paralysis and death of the parasites. Fluralaner kills fleas before they can lay eggs and so helps to reduce contamination of the cats' environment.

Moxidectin kills parasites present in the body of animals such as roundworms, hookworms and heartworm as well as ear mites. Moxidectin causes paralysis and death of these parasites by interfering with the way signals are passed between nerve cells (neurotransmission) in the parasites' nervous system.

Fluralaner and moxidectin are already authorised on their own for the treatment of parasitic infestations.

What benefits of Bravecto Plus have been shown in studies?

A field study involving cats naturally infested with ticks and/or fleas showed treatment with Bravecto Plus to reduce tick and flea counts by more than 95% and to be as effective as treatment using fipronil, another medicine already licensed for the treatment of ticks and fleas.

Another field study involving cats naturally infected with roundworms and/or hookworms showed treatment with Bravecto Plus to reduce faecal egg counts by 100%. Bravecto Plus was as effective as another medicine containing emodepside and praziquantel.

In a field study of 167 cats infested with 5 or more ear mites, treatment with Bravecto Plus resulted in 94% of cats free from ear mites 14 days after treatment and 100% of cats free from ear mites 28 days after treatment. Bravecto Plus was as effective as selamectin, another medicine already licensed for the treatment of ear mites in cats.

Two laboratory studies involving healthy cats which were artificially infected with heartworm larvae showed Bravecto Plus to be 100% effective in preventing heartworm disease during 8 weeks. Further laboratory studies showed that, when given at 12-week intervals, Bravecto Plus is effective at continuously preventing heartworm disease.

What are the risks associated with Bravecto Plus?

The most common side effects with Bravecto Plus (which may affect up to 1 in 10 animals) are mild and short-lived reactions at the application site such as hair loss, flaking skin, redness and scratching.

For the full list of side effects and restrictions of Bravecto Plus, see the package leaflet.

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

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 Plus 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 Plus authorised in the EU?

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

Other information about Bravecto Plus

Bravecto Plus received a marketing authorisation valid throughout the EU on 8 May 2018.

Further information on Bravecto Plus can be found on the Agency's website:

ema.europa.eu/medicines/veterinary/EPAR/bravecto-plus.

This overview was last updated in December 2019.