EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2024
EMA/CVMP/443870/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

BRAVECTO TriUNO

International non-proprietary name (INN): Fluralaner / Moxidectin / Pyrantel

On 10 October 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product BRAVECTO TriUNO, chewable tablet, intended for dogs. The applicant for this veterinary medicinal product is Intervet International B.V.

BRAVECTO TriUNO is an antiparasitic veterinary medicinal product containing a combination of three active substances fluralaner, moxidectin and pyrantel (QP54AB52). Fluralaner is an ectoparasiticide belonging to the isoxazoline group, with inhibitory activity on GABA- and glutamate-gated chloride channel located in nervous system of invertebrates, preventing the postsynaptic uptake of chloride ions by GABA- and glutamate-gated ion channels and thus resulting in depolarization, paralysis and death of the target parasite. Moxidectin belongs to the milbemycin group of macrocyclic lactones and has parasiticidal activity against nematodes. It interferes with neuromuscular transmission of the glutamate-gated chloride channels and of GABA-gated channels, thus leading to the opening of the chloride channels on the postsynaptic junction to allow the inflow of chloride ions which results in flaccid paralysis and eventual death of parasites exposed to the drug. Pyrantel is a nicotinic acetylcholine (ACh) channel receptor (nAChR) agonist; following receptor binding, the channel opens to allow the influx of cations resulting in a depolarization and excitatory effects on nematode muscle, ultimately leading to spastic paralysis of the worm and death.

The benefits of BRAVECTO TriUNO is its efficacy against mixed parasitic infestations by ticks or fleas, gastrointestinal nematodes, lungworm and/or heartworm in dogs.

The most common side effects are digestive tract disorders like diarrhoea and emesis (vomiting).

The full indication is: For dogs with, or at risk from, mixed parasitic infestations by ticks or fleas, gastrointestinal nematodes, lungworm and/or heartworm. The veterinary medicinal product is exclusively indicated when use against ticks or fleas and gastrointestinal nematodes is indicated at the

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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same time. The veterinary medicinal product also provides concurrent efficacy for the prevention of heartworm disease and angiostrongylosis.

For the treatment of tick and flea infestations on dogs providing immediate and persistent flea (*Ctenocephalides felis* and *C. canis*) and tick (*Dermacentor reticulatus, Ixodes hexagonus, I. ricinus,* and *Rhipicephalus sanguineus*) killing activity for 1 month.

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

For reduction of the risk of infection with *Babesia canis canis* via transmission by *D. reticulatus* for 1 month. The effect is indirect due to the veterinary medicinal product's activity against the vector.

For reduction of the risk of infection with *Dipylidium caninum* via transmission by *C. felis* for 1 month. The effect is indirect due to the veterinary medicinal product's activity against the vector.

Treatment of infections with gastrointestinal nematodes of the following species: roundworms (adult stages of *Toxocara canis,* and adult stages of *Toxascaris leonina*) and hookworms (L4, immature adult (L5) and adult stages of *Ancylostoma caninum* and adult stages of *Uncinaria stenocephala*).

Prevention of heartworm disease (caused by *Dirofilaria immitis*).

Prevention of angiostrongylosis (by reduction of the level of infection with immature adult (L5) and adult stages of *Angiostrongylus vasorum*).

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for BRAVECTO TriUNO and therefore recommends the granting of the marketing authorisation.