17 March 2017
EMA/CVMP/159285/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (post-authorisation)

NEXGARD SPECTRA

International non-proprietary name (INN): afoxolaner / milbemycin oxime

On 16 March 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product NEXGARD SPECTRA. The applicant for this veterinary medicinal product is MERIAL.

NEXGARD SPECTRA is a medicinal product containing a fixed combination of afoxolaner / milbemycin oxime (ATCvet code QP54AB51) as active substance, for the treatment of flea and tick infestations in dogs when the concurrent prevention of heartworm disease (*Dirofilaria immitis* larvae), angiostrongylosis (reduction in level of immature adults (L5) and adults of *Angiostrongylus vasorum*) and/or treatment of gastrointestinal nematode infestations is indicated.

The change agreed by the CVMP concerns the addition of the following new therapeutic indications in the target species (dogs):
- prevention of angiostrongylosis (reduction of infestation by *Angiostrongylus vasorum*);
- treatment of infestations with adult gastrointestinal nematodes of hookworms (*Ancylostoma ceylanicum*).

The most common adverse reactions in animals are vomiting, diarrhoea, lethargy, anorexia, and pruritus. This product may cause gastrointestinal disturbances if ingested by the person administering the veterinary medicinal product to animals.

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[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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