7 November 2014
EMA/CVMP/641766/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

NEXGARD SPECTRA

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

On 6 November 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2] recommending the granting of a marketing authorisation for the veterinary medicinal product NEXGARD SPECTRA chewable tablets for dogs, intended for the treatment of flea, tick and gastrointestinal nematode infestations and the prevention of heartworm disease. The applicant for this veterinary medicinal product is MERIAL.

The active substances of NEXGARD SPECTRA are afoxolaner and milbemycin oxime. Afoxolaner is an ectoparasiticide belonging to the isoxazoline group, which is systemically active against ticks and fleas. Milbemycin oxime is an antiparasitic endectocide belonging to the group of macrocyclic lactones. It is active against several nematodes. The tablets are available in five different strengths containing afoxolaner and milbemycin oxime as follows: 9.375 mg / 1.875 mg; 18.75 mg / 3.75 mg; 37.50 mg / 7.5 mg; 75 mg / 15 mg and 150 mg / 30 mg.

The benefits of NEXGARD SPECTRA are its efficacy in the treatment of flea and tick infestations in dogs when the concurrent prevention of heartworm disease and/or treatment of gastrointestinal nematode infestations is indicated. NEXGARD SPECTRA is generally well tolerated at the recommended dose. Uncommonly observed side effects are vomiting, diarrhoea, lethargy, anorexia and pruritus, which are generally self-limiting and of short duration.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) 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 to risk balance for NEXGARD SPECTRA and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact