EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2013
EMA/CVMP/569374/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Vectra 3D

Dinotefuran, pyriproxyfen and permethrin

On 10 October 2013, 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 Vectra 3D spot-on solution for dogs, intended for the treatment and prevention of infestations by fleas (*Ctenocephalides felis* and *Ctenocephalides canis*) and ticks (*Rhipicephalus sanguineus*, *Dermacentor reticulatus*, *Ixodes ricinus*). Vectra 3D is also intended for the prevention of bites from sand flies (*Phlebotomus perniciosus*), mosquitoes (*Culex pipiens*, *Aedes aegypti*) and stable flies (*Stomoxys calcitrans*). The applicant for this veterinary medicinal product is Ceva Santé Animale.

Vectra 3D contains a combination of permethrin with another insecticidal substance, dinotefuran, and an insect growth inhibitor, pyriproxyfen, (ATCvet code: QP53AC54, Permethrin, combinations), and is for topical use on dogs. The insecticidal activity of dinotefuran is due to its interference with the nervous system of the parasites which results in their paralysis and death. Permethrin, a pyrethroid, is an acaricide and insecticide with repellent activity. Pyriproxyfen is an insect growth regulator which acts by mimicking the juvenile hormone and stops the flea life cycle. Vectra 3D is presented as single-dose spot-on applicators and is available in five different strengths.

The benefits of Vectra 3D are its efficacy in dogs for the treatment and prevention of flea and tick infestations, and the prevention of biting from certain specified flies and mosquitoes. The most common side effects are transient erythema, pruritus or other signs of discomfort at the application site, although these have been reported very rarely. Gastrointestinal signs such as vomiting or diarrhoea have also been reported very rarely.

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 Vectra 3D 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.

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