11 April 2014
EMA/CVMP/158566/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Vectra Felis

Dinotefuran and pyriproxyfen

On 10 April 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 Vectra Felis 423 mg/42.3 mg spot-on solution for cats, intended for the treatment and prevention of flea infestations (*Ctenocephalides felis*) in cats. The applicant for this veterinary medicinal product is Ceva Santé Animale.

Vectra Felis contains a combination of an insecticidal substance, dinotefuran, with an insect growth inhibitor, pyriproxyfen, (ATCvet code: QP53AX73, Antiparasitic products, insecticides and repellents, other ectoparasiticides for topical use, pyriproxyfen, combinations), and is intended for topical use on cats. The insecticidal activity of dinotefuran is due to its interference with the nervous system of the parasites which results in their paralysis and death. Pyriproxyfen acts by mimicking the juvenile hormone in fleas and stops the flea life cycle. Vectra Felis is presented as a single-dose spot-on applicator.

The benefits of Vectra Felis are its efficacy in cats for the treatment and prevention of flea infestations. The most common side effects are transient cosmetic effects such as wet hair and a white dry residue which may occur at the application site and may persist up to 7 days. These effects are, however, usually not noticeable after 48 hours. These changes do not affect the safety or the efficacy of the veterinary medicinal product.

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 Felis 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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