10 December 2010
EMA/CVMP/528765/2010
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

ACTIVYL

Indoxacarb

On 8 December 2010, 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 ACTIVYL, 195 mg/ml, spot-on solution, intended for treatment and prevention of flea infestation (*Ctenocephalides felis*). The applicant for this veterinary medicinal product is Intervet International BV.

The active substance of ACTIVYL is Indoxacarb, an ectoparasiticide for topical use, ATCvet QP53AX27, which after bioactivation by insects' enzymes interferes with the nervous system of the parasites and causes paralysis and death.

The benefits of ACTIVYL are its effectiveness in the treatment and prevention of flea infestations in dogs and cats. The most common side effect is hypersalivation if the animal licks the application site.

The approved indication is: *For dogs and cats:*

Treatment and prevention of flea infestation (Ctenocephalides felis)

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

Developing stages of fleas in the pet's immediate surroundings are killed following contact with Activyl treated pets.

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 ACTIVYL 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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