11 November 2011
EMA/CVMP/825805/2011
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1]

Activyl Tick Plus

Indoxacarb and permethrin

On 10 November 2011, 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 Tick Plus, a spot-on solution, intended for the treatment and prevention of infestations by fleas (*Ctenocephalides felis*) and ticks (*Rhipicephalus sanguineus*, *Ixodes ricinus)*.

The applicant for this veterinary medicinal product is Intervet International BV.

The active substances of Activyl Tick Plus are indoxacarb and permethrin, which are ectoparasiticides for topical use, ATCvet code: QP53AC54. Indoxacarb, after bioactivation by insects' enzymes, interferes with the nervous system of the parasites and causes paralysis and death. Permethrin, a pyrethroid, is an acaricide and insecticide with repellent activity.

The benefits of Activyl Tick Plus are its are its effectiveness in the treatment and prevention of flea and tick infestations in dogs. The most common side effects are transitory scratching, erythema or hair loss at the application site.

The approved indication is:

'Treatment of flea infestations (*Ctenocephalides felis*); the product has persistent insecticidal efficacy for up to 4 weeks against *Ctenocephalides felis*.

The product has persistent acaricidal efficacy for up to 5 weeks against *Ixodes ricinus* and up to 3 weeks against *Rhipicephalus sanguineus*. If ticks of these species are present when the product is applied, all the ticks may not be killed within the first 48 hours but they may be killed within a week.

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 Tick Plus treated pets.'

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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 Tick Plus and therefore recommends the granting of the marketing authorisation.