16 June 2017
EMA/CVMP/268590/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Exzolt

International non-proprietary name (INN): fluralaner

On 15 June 2017, 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 Exzolt, 10 mg/ml solution for use in drinking water, intended for the treatment of poultry red mite (*Dermanyssus gallinae*) infestation in chickens. The applicant for this veterinary medicinal product is Intervet International B.V.

Exzolt is an antiparasitic medicinal product containing fluralaner (ATCvet code QP53BE02) as the active substance. Fluralaner is an isoxazoline ectoparasiticide which is systemically active against the mites.

The benefits of Exzolt are its efficacy in the treatment of poultry red mite (*Dermanyssus gallinae*) infestation in chickens (pullets, breeders and layer hens).

Exzolt is well tolerated at the recommended dose.

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-risk balance for Exzolt 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 67 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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