22 March 2019
EMA/CVMP/149492/2019
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Afoxolaner MERIAL

International non-proprietary name (INN): afoxolaner

On 21 March 2019, 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 Afoxolaner MERIAL, chewable tablets, intended for use in dogs. The applicant for this veterinary medicinal product is MERIAL.

Afoxolaner MERIAL is an antiparasitic medicinal product containing afoxolaner (ATCvet code QP53BE01) as active substance, which acts at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarines.

The benefits of Afoxolaner MERIAL are its efficacy in the treatment of flea and tick infestations, demodicosis and sarcoptic mange in dogs; the product can also be used as part of a treatment strategy for the control of flea allergy dermatitis in dogs. The most common side effects are mild gastrointestinal effects (vomiting, diarrhoea), pruritus, lethargy, anorexia, and neurological signs (convulsions, ataxia and muscle tremors), which have been reported very rarely.

The application for Afoxolaner MERIAL was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Afoxolaner MERIAL is NexGard (EU/2/13/159/001-016).

The full indication is:

- Treatment of flea infestation in dogs (*Ctenocephalides felis* and *C. canis*) for at least 5 weeks. The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).
- Treatment of tick infestation in dogs (*Dermacentor reticulatus*, *Ixodes ricinus*, *Rhipicephalus*

[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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sanguineus). One treatment kills ticks for up to one month.
Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

- Treatment of demodicosis (caused by *Demodex canis*).
- Treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*).

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 for the reference product NexGard and the informed consent accepted for this application, considers that there is a favourable benefit-risk balance for Afoxolaner MERIAL and therefore recommends the granting of the marketing authorisation.